

APPENDIXES

Appendix A: Search Strategy

Question 3. How do provider/hospital characteristics affect outcomes overall and differentially (e.g., geographic region and volume)?

Search Strings	Studies Identified
"Outcome assessment (health care)"[MeSH] AND "prostatic neoplasms"[MeSH] AND hospital volume	29
"Outcome assessment (health care)"[MeSH] AND "prostatic neoplasms"[MeSH] AND surgeon volume	11
"Cryotherapy"[MeSH] AND "prostatic neoplasms"[MeSH] AND "outcome and process assessment (health care)"[MeSH]	7
"Brachytherapy"[MeSH] AND "prostatic neoplasms"[MeSH] AND "outcome and process assessment (health care)"[MeSH]	249
"Radiotherapy"[MeSH] "prostatic neoplasms"[MeSH] AND "outcome and process assessment (health care)"[MeSH]	624
"Radiotherapy"[MeSH] "Prostatic Neoplasms"[MeSH] AND "outcome and process assessment (health care)"[MeSH] AND hospital volume	9
"Prostatic neoplasms"[MeSH] AND "outcome and process assessment (health care)"[MeSH] AND "prostatectomy"[MeSH], Limits: humans, English, published from 01/01/1993 to 01/12/2005	702
"Health care quality, access, and evaluation"[MeSH] AND "prostatic neoplasms"[MeSH] AND hospital volume	100
"Health care quality, access, and evaluation"[MeSH] AND "prostatic neoplasms"[MeSH] AND "clinical competence"[MeSH]	6
"Prostatic neoplasms"[MeSH] AND "clinical competence"[MeSH]	47
Physician's practice patterns"[MeSH] AND "prostatic neoplasms"[MeSH] Limit: human, English	142
"Health services research/organization and administration"[MeSH] OR "health Services research/standards"[MeSH] OR "health services research/statistics and numerical data"[MeSH] OR "health services research/trends"[MeSH]) AND "prostatic neoplasms"[MeSH]	20
"United States/epidemiology"[MeSH] AND "prostatic neoplasms"[MeSH] NOT review, English, human	608
"Physicians"[MeSH] AND "prostatic neoplasms"[MeSH]	20
"Hospitals"[MeSH] AND "prostatic neoplasms"[MeSH] NOT review NOT letter NOT editorials	75
"Prostatic neoplasms"[MeSH] AND "malpractice"[MeSH]	17
Hospital volume AND prostate cancer	132
"Prostatic neoplasms"[MeSH] AND "learning curve" Limits: English, humans	67
"Physicians"[MeSH] AND "prostatic neoplasms"[MeSH] AND "learning curve" Limits: English, humans	0
"Prostatic neoplasms"[MeSH] AND "learning curve" Limits: English, randomized controlled trial, humans	0
"Prostatic neoplasms"[MeSH] AND "learning curve"	84

Appendix A: Search Strategy (continued)

Quality of Life. The literature search was done on MEDLINE (via OVID) using the following combination of MeSH headings, keywords, and publication types (search results were limited to: human studies; English-language articles; year of publication = 2000 to 2006; not comments, letters or reviews; and clinical trials, clinical trials phase I, clinical trials phase II, clinical trials phase III, clinical trials phase IV, controlled clinical trials, meta analyses, or randomized controlled trials):

((((quality of life or qol or hrqol).mp. OR exp "quality of life"/ OR health status.mp. OR exp health status/) AND exp prostatic neoplasms/) NOT (metastat\$ or advanced).mp.)

HIFU. The literature search was done on PubMed using the following combination of MeSH headings, keywords and limits:

"Prostatic Neoplasms"[MeSH] AND "Ultrasound, High-Intensity Focused, Transrectal"[MeSH] Limits: English, Clinical Trial, Randomized Controlled Trial, Male, Humans

IMRT. The literature search was done on PubMed using the following combination of MeSH headings, keywords and limits:

"Prostatic Neoplasms"[MeSH] AND "Radiotherapy, Intensity-Modulated"[MeSH] NOT review NOT case-reports NOT letter NOT editorial Limits: Entrez Date from 2004/01/01 to 2007/04/31, English, Clinical Trial, Randomized Controlled Trial, Male, Humans

PBRT. The literature search was done on PubMed using the following combination of MeSH headings, keywords and limits:

("Prostatic Neoplasms/radiotherapy"[MeSH] OR "Prostatic Neoplasms/therapy"[MeSH]) AND proton NOT Review NOT Comment NOT letter NOT editorial NOT Case-reports Limits: English, Clinical Trial, Randomized Controlled Trial, "Clinical Trial, Phase II", "Clinical Trial, Phase III", "Clinical Trial, Phase IV", Comparative Study, Male, Humans

Cryosurgery. The literature search was done on PubMed using the following combination of MeSH headings, keywords and limits:

"Prostatic Neoplasms"[MeSH] AND "Cryosurgery"[MeSH] NOT Review NOT Comment NOT letter NOT editorial NOT Case-reports Limits: English, Clinical Trial, Randomized Controlled Trial, Male, Humans

Laparoscopic Surgery. The literature search was done on PubMed using the following combination of MeSH headings, keywords and limits:

"Prostatic Neoplasms"[MeSH] AND "Laparoscopy"[MeSH] AND "Prostatectomy" [MeSH] NOT Review NOT Comment NOT letter NOT editorial NOT Case-reports Limits: English, Clinical Trial, Randomized Controlled Trial, Male, Humans

Robotic Surgery. The literature search was done on PubMed using the following combination of MeSH headings, keywords and limits:

"Prostatic Neoplasms"[MeSH] AND "Robotics"[MeSH] AND "Prostatectomy"[MeSH] NOT Review NOT Comment NOT letter NOT editorial NOT Case-reports Limits: English, Clinical Trial, Randomized Controlled Trial, Male, Humans

Appendix B: Peer Reviewers

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Appendix C: Evidence Tables and Figures

Figure C1. Flow of articles reviewed

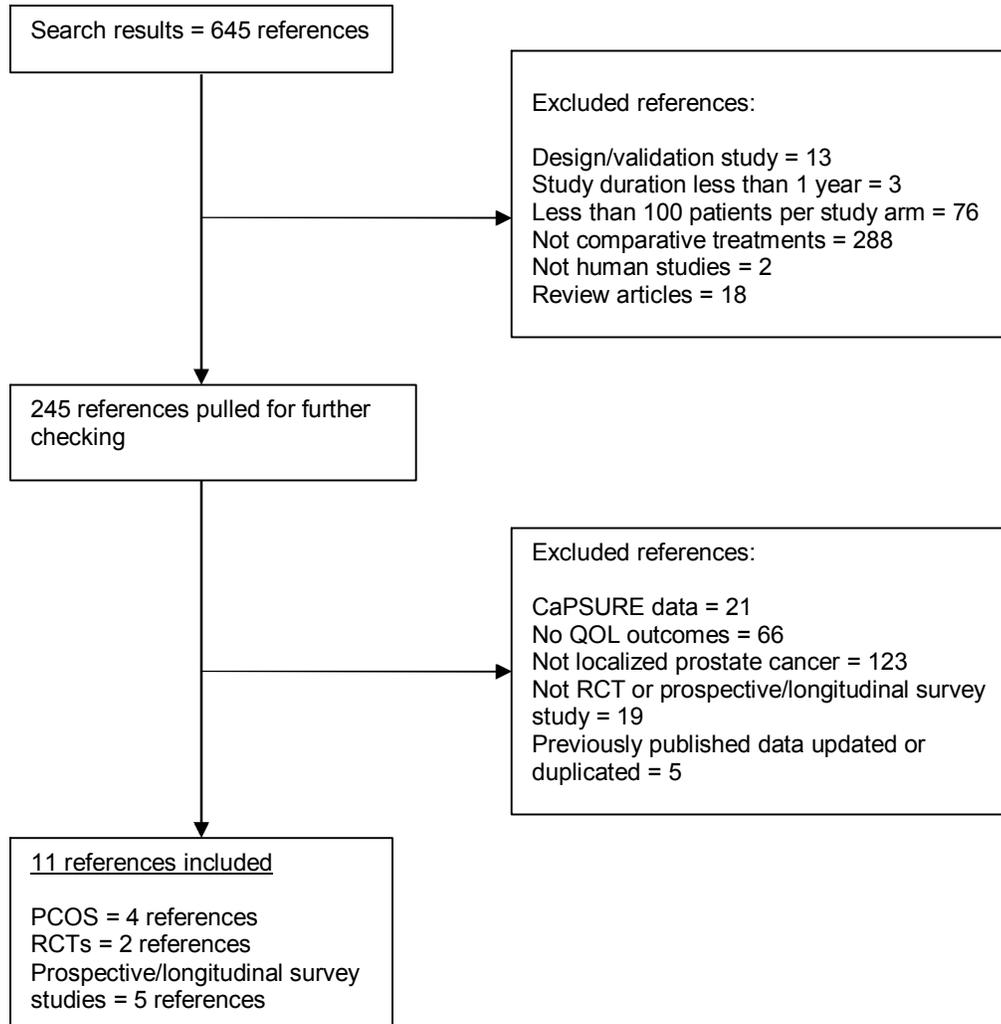


Table C1. Disease specific mortality or survival for randomized controlled trials

Study Outcomes	Treatment Group	Control Group	Analyses; p-values
RP compared to WW			
Bill-Axelson, 2005 ¹	RP (n=347)	Watchful waiting (n=348)	p value Absolute risk reduction (ARR) [95% CI] Relative risk (RR) [95% CI]
Total number of PC deaths	30	50	0.01
Cumulative Incidence of death	2.3% [1.2 to 4.6]* at 5 years 9.6% [6.5 to 14.2] at 10 years	4.3% [2.6 to 7.1] at 5 years 14.9% [11.2 to 19.8] at 10 years	ARR: 2.0 [-0.6 to 4.7] at 5 years ARR: 5.3 [-0.3 to 11.0] at 10 years RR: 0.56 [0.36 to 0.88] at 10 years
Median followup: 8.2 years			
RP compared to RP combined with neoadjuvant ADT			
Klotz, 2003 ²	RP (n=101)	RP + neoadjuvant ADT (n=112)	
Total number of PC deaths	0	1	
Median followup: 6 years (0.6 to 9.8)			
EBRT, comparison of different regimens			
Yeoh, 2006 ³	Hypofractionated (55 Gy) EBRT group (n=108)	Conventional (64 Gy) EBRT (n=109)	
Total number of PC deaths	1	3	
Median followup: 4 years (0.5 to 9)			
Lukka, 2005 ⁴	Long arm (66 Gy) EBRT (n=470)	Short arm (52.5 Gy) EBRT (n=466)	
Total number of PC deaths	3 (<1%)	0	
Median followup: 5.7 years (4.5 to 8.3)			
Yeoh, 2003 ⁵	Conventional (64 Gy) EBRT (n=61)	Hypofractionated (55 Gy) EBRT (n=59)	
Total number of PC deaths	1 (1.6%)	0	
Median followup: 3.6 years (1.9 to 5.2)			
Zietman, 2005 ⁶	Conventional dose (70 Gy) EBRT (n=197)	High dose (79.2 Gy) EBRT (n=196)	
Total number of PC deaths	2	0	
Median followup: 5.5 years (1.2 to 8.2)			

Table C1. Disease specific mortality or survival for randomized controlled trials (continued)

Study Outcomes	Treatment Group	Control Group	Analyses; p-values
EBRT combined with ADT compared to EBRT alone			
Denham, 2005 ⁷	EBRT (66 Gy) (n=164, T2 only)	EBRT (66 Gy) Group + 6 months ADT (n=162, T2 only)	HR [95% CI]
Total number of PC deaths: T2b	5	1	0.22 [0.03 to 1.88]
Total number of PC deaths: T2c	12	7	0.57 [0.22 to 1.44]
Median followup: 5.9 years (0.1 to 8.5)			
D'Amico, 2004 ⁸	Conformal EBRT (70 Gy) (n=103)	Conformal EBRT (70 Gy) + adjuvant ADT (n=98)	p value
Total number of PC deaths	6	0	0.02
Median followup: 4.5 years			
Vaccine compared to nilutamide			
Arlen, 2005 ⁹	Vaccine Group (n=21)	Nilutamide Group (n=21)	
Total number of deaths	1**	4**	

* 95% Confidence intervals
 ** Includes crossover deaths

Table C2. Biochemical progression/reoccurrence or bNED for randomized controlled trials

Study Outcomes	Treatment Group	Control Group	Analyses; p-values
RPwith or without ADT compared to RP combined with neoadjuvant ADT			
Homma, 2004 ¹⁰	Definition of biochemical progression/reoccurrence or bNED: PSA above the normal level, local reoccurrence, or distant metastases.		
	RP + adjuvant ADT (n=63, stage A and B)	RP + neoadjuvant and adjuvant ADT (n=69, stage A and B)	p value
Clinical relapse events at 5 years	9 1/12 stage A 8/51 stage B	11 0/9 stage A 11/60 stage B	<0.05 relapse vs. no relapse
Klotz, 2003 ²	Definition of biochemical progression/reoccurrence or bNED: Two consecutive detectable PSAs (>2.0 ng/ml) at least 4 weeks apart, re-treatment or death from prostate cancer.		
	RP (n=101)	RP + neoadjuvant ADT (n=112)	Hazard ratio [95% CI*]
Biochemical reoccurrence events at 6 years	34 (33.7%)	42 (37.5%)	0.98 [0.61; 1.56]
Gleason score at biopsy: 2-6			1.00
7			1.29 [0.72; 2.31]
8-10			2.82 [1.52; 5.22]
			p value
No evidence of bNED at 5 years	68.2% [58.5; 77.8]	60.2% [50.4 to 70.0]	0.73
Estimated bNED survival at 7 years:			
Gleason: 2-6 (n=142)	0.90	0.89	0.81
7 (n=36)	0.75	0.90	0.91
8-10 (n=22)	0.63	0.79	0.80
Median followup: 6 years (0.6 to 9.8)			
Schulman, 2000 ¹¹	Definition of biochemical progression/reoccurrence or bNED: Increase in PSA on 2 consecutive occasions of >1.0 ng/ml		
	RP (n=115, T2 only)	RP + neoadjuvant ADT (n=105, T2 only)	p Value
PSA progression >1 ng/ml events at 4 years	26/114 (22.8%) T2 and PSA <20 ng/ml 16/94 (17.0%)	18/102 (17.6%) T2 and PSA <20 ng/ml 13/84 (15.4%)	0.35 0.78
Soloway, 2002 ¹²	Definition of biochemical progression/reoccurrence or bNED: PSA >0.4 ng/ml		
	RP (n=154)	RP + neoadjuvant ADT (n=149)	p value
Biochemical reoccurrence at 5 years			
Gleason, biopsy: 2-6 (n=159)	22/80 (27.1%)	18/79 (22.6%)	0.62
7 (n=56)	10/25 (41.3%)	15/31 (47.7%)	0.72
8-10 (n=29)	8/14 (57.4%)	13/15 (89.6%)	0.173
Gleason, specimen: 2-6 (n=105)	18/66 (27.1%)	10/39 (26.0%)	1.0
7 (n=96)	17/48 (38.9%)	15/48 (30.5%)	0.54
8-10 (n=38)	4/12 (33.7%)	17/26 (64.6%)	0.13
bNED at 5 years	67.6%	64.8%	0.66

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Table C2. Biochemical progression/reoccurrence or bNED for randomized controlled trials (continued)

Study Outcomes	Treatment Group	Control Group	Analyses; p-values
RP compared to EBRT			
Paulson, 1982 ¹³	Definition of biochemical progression/reoccurrence or bNED: Serum prostatic acid phosphatase elevation on 2 consecutive followups or by appearance of bony or parenchymal disease with or without concomitant acid phosphatase elevation.		
	RP (n=47)	EBRT (n=59)	p value
K-M estimate of failure at 5 years	14% (estimated from graph)	39% (estimated from graph)	0.037
EBRT, comparison of different regimens			
Peeters, 2006 ¹⁴	Definition of biochemical progression/reoccurrence or bNED: Defined according to ASTRO -3 consecutive increases in PSA level after nadir or clinical evidence of failure (palpable and/or biopsy proven local relapse, regional relapse, metastases, or initiation of salvage		
	Conventional dose (68 Gy) EBRT group (n=56 Low risk T1/2; Gleason ≤6; PSA ≤10)	High dose (78 Gy) EBRT group (n=64 Low risk T1/2; Gleason ≤6; PSA ≤10)	HR [95% CI]
Biochemical reoccurrence/clinical failure events			
Median followup: 4.2 years (0.8 to 7.6)	7/56 (12.5%)	10/64 (15.6%)	1.25 [0.5; >2.0] (estimated from figure)
Yeoh, 2003 ⁵	Definition of biochemical progression/reoccurrence or bNED: 3 consecutive increases in PSA after nadir		
	Hypofractionated (55 Gy) EBRT group (n=108)	Conventional (64 Gy) EBRT (n=109)	p value HR [95% CI]
PSA relapse events	37	39	Not significant
K-M estimate of biochemical relapse-free survival at 5 years	57.4%	55.5%	HR: 0.92 [0.58; 1.45]
Lukka, 2005 ⁴	Definition of biochemical progression/reoccurrence or bNED: 3 consecutive increases in PSA, clinical evidence of failure (local and distant), initiation of hormonal therapy		
	Short arm (52.5 Gy) EBRT (n=466)	Long arm (66 Gy) EBRT (n=470)	ARR [95% CI], HR [95% CI]
Biochemical or clinical failure (BCF) events	263 (56.4%)	236 (50.2%)	
K-M estimate of BCF at 5 years	59.95%	52.95%	ARR: -7.0 [-12.6; -1.4]
Median followup: 5.7 years (4.5 to 8.3)			HR: 1.18 [0.99; 1.41]
Sathya, 2005 ¹⁵	Definition of biochemical progression/reoccurrence or bNED: PSA failure, clinical failure, or death from prostate cancer		
	Iridium implant + EBRT (n=31, T2 only)	EBRT (n=32, T2 only)	HR [95% CI]
BCF events	8	18	0.37 [0.16; 0.85]
K-M estimate of BCF at 5 years			
Median followup: 8.2 years	25.8%	57.3%	
Zietman, 2005 ⁶	Definition of biochemical progression/reoccurrence or bNED: 3 consecutive increases in PSA level, with the failure backdated to a point halfway between the first increase and the last nonincreasing value		
	Conventional dose (70 Gy) EBRT (n=197)	High dose (79.2 Gy) EBRT (n=196)	p value
Freedom from biochemical failure at 5 years	61.4% [54.6 to 68.3]	80.4% [74.7; 86.1]	<0.001
Median followup: 5.5 years (1.2 to 8.2)			
EBRT combined with ADT compared to EBRT alone			
Denham, 2005 ⁷	Definition of biochemical progression/reoccurrence or bNED: Based on Houston method. Time to failure is time from end		

Table C2. Biochemical progression/reoccurrence or bNED for randomized controlled trials (continued)

Study Outcomes	Treatment Group	Control Group	Analyses; p-values
	of treatment to an increase of PSA ≥ 2 ng/ml above the post-treatment nadir level.		
	EBRT (66 Gy) (n=164, T2 only)	EBRT (66 Gy) + 6 months ADT (n=162, T2 only)	HR [95% CI]
Failure events: T2b	48	34	0.68 [0.44; 1.06]
Failure events: T2c	66	40	0.47 [0.32; 0.69]
Median followup: 5.9 years (0.1 to 8.5)			
Crook, 2004 ¹⁶	Definition of biochemical progression/reoccurrence or bNED: Biochemical (PSA) disease-free survival according to ASTRO definition.		
	3 month group (n=51, Low risk T1c-T2a; PSA <10 ng/ml; Gleason ≤ 6)	8 month group (n=41, Low risk T1c-T2a; PSA <10 ng/ml; Gleason ≤ 6)	
K-M estimate of freedom from biochemical failure at 5 years Median followup: 3.7 years (10 months-7 years)	61% (estimated from graph)	72% (estimated from graph)	p-value not noted
D'Amico, 2004 ⁸	Definition of biochemical progression/reoccurrence or bNED: PSA >1.0 ng/ml and increasing >0.2 ng/ml on 2 consecutive visits.		
	Conformal EBRT (70 Gy) group (n=103)	Conformal EBRT (70 Gy) + adjuvant ADT (n=98)	p value HR [95% CI]
PSA failure events	46	21	<0.001 2.86 [1.69; 4.86]
Survival free of salvage ADT events	43	21	0.002
K-M estimated salvage therapy free survival at 5 years Median followup: 4.5 years	57% [46; 69]	82% [73; 90]	2.30 [1.36; 3.89]
Brachytherapy			
Wallner, 2003 ¹⁷	Definition of biochemical progression/reoccurrence or bNED: PSA ≤ 0.5 ng/ml at last followup		
	¹²⁵ I (144 Gy) (n=57)	¹⁰³ Pd (125 Gy) (n=58)	p value
Biochemical failure events	6	5	
KM estimated biochemical freedom from failure at 3 years	89%	91%	0.76

Table C2. Biochemical progression/reoccurrence or bNED for randomized controlled trials (continued)

Study Outcomes	Treatment Group	Control Group	Analyses; p-values
Adjuvant EBRT combined with brachytherapy			
Wallner, 2005 ¹⁸	Definition of biochemical progression/reoccurrence or bNED: PSA ≤ 0.5 ng/ml at last followup		
	¹⁰³ Pd + EBRT (20 Gy) (n=83)	¹⁰³ Pd + EBRT (44 Gy) (n=76)	p value
Biochemical failure events	12	9	
K-M estimated biochemical freedom from failure at 3 years	83%	88%	0.64
Subjects with pretreatment PSA <10 ng/ml (n=112)			
K-M estimated biochemical freedom from failure at 3 years	84%	94%	0.16
Subjects with pretreatment PSA >10 ng/ml (n=47)			
K-M estimated biochemical freedom from failure at 3 years	82%	72%	0.38
Bicalutamide versus placebo; both treatment arms combined with standard care (adjuvant RP/EBRT or WW)			
Wirth, 2004 ¹⁹	Definition of biochemical progression/reoccurrence or bNED: Progression-free survival defined as the time from randomization to the earliest occurrence of objective progression (confirmed by bone scan, computerized tomography/ultrasound/MRI or histological evidence of distant metastases) or death from any cause.		
Localized disease population (T1/T2)	Bicalutamide and radical prostatectomy (<i>estimated n=1365</i>)	Placebo and radical prostatectomy (<i>estimated n=1,369</i>)	p value HR [95% CI] Event-to-time ratio (ETR) [95% CI]
Progression events	115 (8.4%)	121 (8.8%)	0.57
Median followup: 5.4 years			HR: 0.93 [0.72 to 1.20] ETR: 1.06 [0.87 to 1.28]
	Bicalutamide and radiation therapy (<i>estimated n=538</i>)	Placebo and radiation therapy (<i>estimated n=527</i>)	
Progression events	114 (21.2%)	128 (24.3%)	0.09
Median followup: 5.4 years			HR: 0.80 [0.62; 1.03] ETR: 1.16 [0.98; 1.37]
Vaccine compared to nilutamide			
Arlen, 2005 ⁹	Definition of biochemical progression/reoccurrence or bNED: PSA progression, the development of secondary malignancies or toxicity, and were either removed from study or crossed over to the other arm if time it was an appropriate time to do so		
	Vaccine Group (n=21)	Nilutamide Group (n=21)	p value
Median time to treatment failure, in months	9.9	7.6	0.28
	Crossover: 12 subjects had added nilutamide 13.9 after crossover, 25.9 from initiation of therapy	Crossover: 8 subjects had added vaccine 5.2 after crossover, 15.5 from initiation of therapy	

* Confidence intervals

Table C3. Definitions of biochemical progression/reoccurrence or bNED for randomized controlled trials

Study	Definition
Paulson, 1982 ¹³	Acid phosphatase elevation on 2 consecutive followups or by appearance of bony or parenchymal disease with or without concomitant acid phosphatase elevation
Homma, 2004 ¹⁰	Clinical relapse defined as PSA above the normal level, local reoccurrence, or distant metastases
Klotz, 2003 ²	Biochemical reoccurrence defined as 2 consecutive detectable PSAs (>2.0 ng/ml) at least 4 weeks apart, re-treatment or death from prostate cancer
Schulman, 2000 ¹¹	PSA progression defined as an increase in PSA on 2 consecutive occasions of >1.0 ng/ml
Soloway, 2002 ¹²	Biochemical reoccurrence defined as PSA >0.4 ng/ml
Lukka, 2005 ⁴	Biochemical or clinical failure was defined as 3 consecutive increases in PSA, clinical evidence of failure (local and distant), initiation of hormonal therapy, or death from prostate cancer
Sathya, 2005 ¹⁵	Biochemical or clinical failure was defined as PSA failure, clinical failure, or death from prostate cancer
Yeoh, 2003 ⁵	PSA relapse defined as 3 consecutive increases in PSA after nadir
Zietman, 2005 ⁶	American Society for Therapeutic Radiology and Oncology (ASTRO) definition of 3 consecutive increases in PSA level, with the failure backdated to a point halfway between the first increase and the last nonincreasing value
Crook, 2004 ¹⁶	Freedom from failure was biochemical (PSA) disease-free survival according to ASTRO definition
D'Amico, 2004 ⁸	PSA failure defined as PSA >1.0 ng/ml and increasing >0.2 ng/ml on 2 consecutive visits
Wallner, 2003 ¹⁷	Freedom from biochemical failure was defined as PSA ≤0.5 ng/ml at last followup
Wallner, 2005 ¹⁸	Freedom from biochemical failure was defined as PSA ≤0.5 ng/ml at last followup
Wirth, 2004 ¹⁹	Progression free survival defined as the time from randomization to the earliest occurrence of objective progression (confirmed by bone scan, computerized tomography/ultrasound/MRI or histological evidence of distant metastases) or death from any cause
Arlen, 2005 ⁹	Treatment failure defined as PSA progression, the development of secondary malignancies or toxicity, and were either removed from study or crossed over to the other arm if time it was an appropriate time to do so

Table C4. Incidence of distant metastatic disease for randomized controlled trials

Study Outcomes	Treatment Group	Control Group	Analyses; p-values
WW versus RP			
Bill-Axelsson, 2005 ¹	RP (n=347)	WW (n=348)	p value ARR [95% CI] RR [95% CI] 0.004
Total number of events	50	79	
Cumulative incidence of metastases	8.1% [5.7; 11.6]* at 5 years	9.8% [7.1; 13.5] at 5 years	ARR: 1.7 [-2.5; 6.0] at 5 years
Median followup: 8.2 years	15.2% [11.4; 20.3] at 10 years	25.4% [20.4; 31.5] at 10 years	ARR: 10.2 [3.1; 17.2] at 10 years RR: 0.60 [0.42; 0.86] at 10 years
RP versus radiation therapy			
Paulson, 1982 ¹³	RP (n=47)	Radiation therapy (n=59)	
Total number of events at followup (time unclear)	2 (positive bone scan)	14 (positive bone scan (11); pulmonary metastases (1); lymph node metastases (1); parenchymal metastases (1))	
RP with or without neoadjuvant therapy			
Klotz, 2003 ²	RP (n=101)	Neoadjuvant androgen ablation + RP (n=112)	p value
Total number of events	1	5	0.21
Median followup: 6 years (0.6 to 9.8)			
Schulman, 2000 ¹¹	RP (n=115, T2 only)	Neoadjuvant androgen ablation + RP (n=105, T2 only)	p value
Total number of events at 4 years	6/114 (5%)	6/102 (6%)	0.84
Soloway, 2002 ¹²	RP (estimated n=135)	Neoadjuvant androgen ablation + RP (estimated n=133)	p value
Events at 5 years			
urethral margin involvement	23 (17%)	8 (6%)	<0.01
seminal vesicle involvement	30 (22%)	20 (15%)	Not significant
positive lymph nodes	9 (6%)	8 (6%)	Not significant
EBRT			
Lukka, 2005 ⁴	Long arm (66 Gy in 33 fractions) EBRT (n=470)	Short arm (52.5 Gy in 20 fractions) EBRT (n=466)	
Distant failure events	4 (1%)	10 (2%)	
Median followup: 5.7 years (4.5 to 8.3)			
Vaccine versus nilutamide			
Arlen, 2005 ⁹	Vaccine Group (n=21)	Nilutamide Group (n=21)	
Progressive disease (metastasis on scans)	14 (5 events after crossover addition of nilutamide)	7 (1 event after crossover addition of nilutamide)	p value not provided

* 95% Confidence intervals

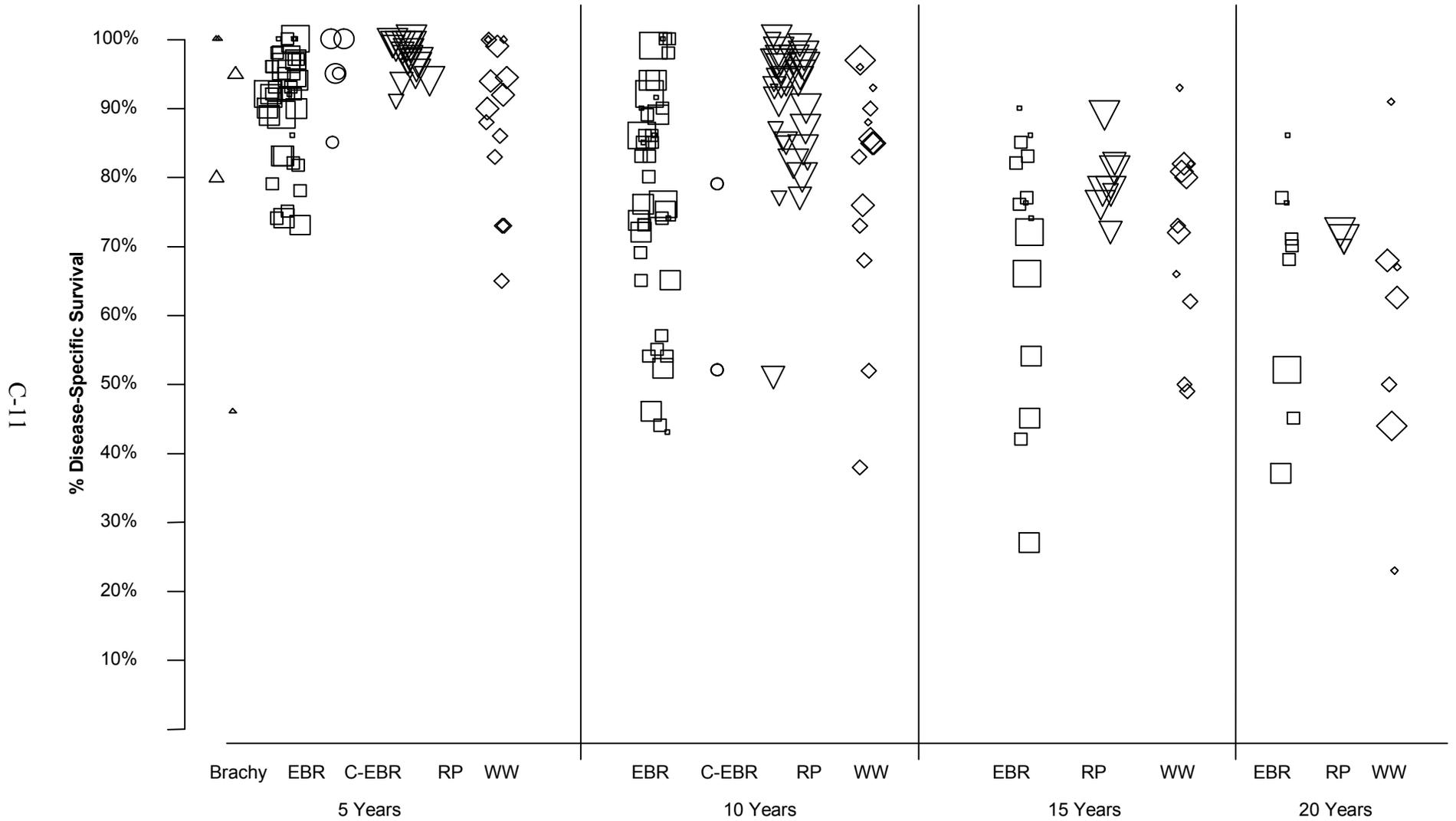
Table C5. Definitions of toxicity for randomized controlled trials

Study	Definition
Lukka, 2005 ⁴	Toxicity was assessed using National Cancer Institute of Canada toxicity scale, grading according to specific criteria for each symptom on a 5-point scale ranging from 0 (nontoxic) to 5 (severe toxicity). Gastrointestinal (GI) system included anorexia, diarrhea, GI bleeding, nausea, pain/cramping, proctitis, and vomiting. Genitourinary (GU) system included bladder changes, cystitis, fistula formation, frequency, hematuria, ureteral obstruction, and genitourinary pain.
Yeoh, 2003 ⁵	GI symptoms were assessed by questionnaire: stool frequency, stool consistency, rectal pain, rectal mucus discharge, urgency of defecation, and rectal bleeding. Each symptom was graded on a on a 5-point scale ranging from 0 (nontoxic) to 4 (severe). The following GU symptoms were evaluated: urinary frequency by day, urinary frequency by night, hematuria, urgency of urination, and dysuria. Each symptom was graded on the same basis as the GI symptoms.
Zietman, 2005 ⁶	Acute GU and GI morbidity were scored using the Radiation Therapy Oncology Group (RTOG) criteria, a 0 to 5 scale in which lower scores indicate fewer symptoms.
D'Amico, 2004 ⁸	Toxicity grades are defined as Grade 1- mild, Grade 2 - moderate, Grade 3 - severe, Grade 4 – life threatening. From Trotti et al, Common toxicity criteria: version 2.0: an improved reference for grading the acute effects of cancer treatment: impact on radiotherapy. <i>Int J Radiat Oncol Biol Phys.</i> 2000;47:13-47.
Herstein, 2005 ²⁰ Wallner, 2003 ¹⁷	RTOG criteria. Persistent bleeding was defined as lasting more than one month and was noted as a Grade 2 morbidity.

Table C6. Intra-operative outcomes and positive margins after laparoscopic vs. open retropubic radical prostatectomy

Outcomes	LRP, %	RRP, %	OR LRP vs. RRP (95% CI)
Pelvic lymphadenectomy	40	45	0.82 (0.47; 1.43)
Bilateral nerve sparing	41.6	51.6	0.67 (0.38; 1.17)
Monolateral nerve sparing	18.3	13.3	1.46 (0.68; 3.15)
Autologous transfusion (no)	13.3	45	0.19 (0.09; 0.38)
First flatus (%)	35	18	2.45 (1.27; 4.72)
Mobilization (%)	92	82	2.52 (1.04; 6.11)
Free ambulation (%)	23	10	2.69 (1.21; 6.00)
5-day catheterization	86.6	66.6	3.24 (1.59; 6.59)
Discharged on postoperative day 6 (with or without catheter)	90	86.6	1.39 (0.58; 3.33)
Positive margins, T2	24.4	18.25	1.45 (0.73; 2.86)

Figure C2. Disease-specific survival at time points by treatment



Brachy = Brachytherapy; EBR = External Beam Radiotherapy; C-EBR = Conformal External Beam Radiotherapy; RP = Radical Prostatectomy; WW = Watchful Waiting
 Point size indicates N, <50 (smallest), 50-150 (next smallest) 150-300 (next largest) and >300 (largest)

Table C7. Complication counts

Type of Complication	Time Period ^a	Used in Graphs ^c		Entire Database ^d	
		Number of Reports	Number of Descriptions	Number of Reports	Number of Descriptions
Bowel	≤6 months	6	3	17	30
Bladder	≤6 months	4	2	30	72
Erectile dysfunction	≤6 months	3	2	15	16
Bowel	6-24 months	2	3	12	23
Bladder	6-24 months	3	2	21	52
Erectile dysfunction	6-24 months	6	2	17	26
Bowel	>24 months	0	0	11	19
Bladder	>24 months	3	4	14	21
Erectile dysfunction	>24 months	5	2	12	9
Other	>24 months	0	0	3	8
Bowel	999	3	2	34	53
Bladder	999	14	3	51	109
Erectile dysfunction	999	5	1	24	46
Bowel	Any ^b	5	3	57	87
Bladder	Any ^b	19	6	79	203
Erectile dysfunction	Any ^b	13	2	44	79
Other	Any ^b			47	129

^a The latest month reported was selected for each report/group combination, or each report

^b Maximum of 4 per report/group combination or report

^c Definitions selected had 3 or more reports associated with them, needed to have percent with complication data, and were selected by treatment. Graphs include report/group combinations.

^d All treatments and combinations of treatments are included in these numbers, report/group combinations were not used.

Table C8. Outcomes after cryosurgical prostatectomy in patients with localized prostate cancer

Reference Design	Population Followup Definition of Outcome	Treatment	Outcome	Occurrence
Aus, 2002 ²¹ Prospective phase noncontrolled II trial	54 patients without metastases, mean age 68 years, mean PSA 26 ng/ml 40.7% with T >2, 37.04% with Gleason scores >7, median followup 58.5 months. Treatment failure: positive biopsy or a serum PSA of >1 ng/ml	Liquid nitrogen system CMS AccuProbe 450 (CryoMedical Science Inc., Rockville, MD). The total operation time 90-180 minutes, mean 148 minutes, freezing time 33 minutes, length of stay 1.2 days	Progression free survival	19 (38.9%)
			Tissue sloughing	14.81%
			TURP resection of sloughed tissue	14.81%
			Stricture	16.67%
			Stone formation in prostatic urethra	9.26%
			Urinary tract infection	33.33%
			Perennial fistula/prostatic abscess	1.85%
			Self reported impotence	72.22%
			Self reported potency	7.41%
			Not reported potency	20.37%
			Incontinence	
			Severe (>2 pads per day)	1.85%
			Mild (1-2 pads per day)	16.67%
Lee, 1994 ²² Case series	210 patients with localized or locally advanced prostate cancer	3.4 mm diameter cryoprobes (Endocare, Inc., Irvine, CA) inserted transperineally into the prostate under the transrectal ultrasound control	Urethrorectal fistula	2.4%
			Bladder outlet obstruction	3%
			Incontinence	9%
			Impotence	40%
			Total complications	14%
Bahn, 2002 ²³ Case series	590 consecutive patients with localized or locally advanced prostate cancer, mean age 70.76 years, 1.8% - T1, 78.1% - T2, 52.5% with Gleason score of 7, and 6% >7, mean followup 5.43 years, Treatment failure: PSA level >1 and >0.5 ng/ml	3.4 mm diameter cryoprobes (Endocare, Inc., Irvine, CA) inserted transperineally into the prostate under the transrectal ultrasound control. Androgen ablation therapy 91.5% before treatment 3 months to 1 year before cryoablation	Biochemical disease free survival	89-100%
			PSA <0.5	Low risk group (T1-2)
			12 months	19.49%
			24 months	16.53%
			36 months	15.47%
			48 months	14.62%
			60 months	12.92%
			72 months	9.53%
			84 months	6.78%
			Impotency of 373 potent before surgery	354 (94.9%)
			16.4 months after surgery	19 (5.1%)
			Incontinence	4.3%
TURP	5.5%			
Fistula	<0.1%			

Table C8. Outcomes after cryosurgical prostatectomy in patients with localized prostate cancer (continued)

Reference Design	Population Followup Definition of Outcome	Treatment	Outcome	Occurrence
Cohen, 1996 ²⁴ Non controlled clinical trial	383 patients with localized or locally advanced prostate cancer 28% with T >2, 7.9 Mean PSA 10 ng/ml 53% with Gleason ≥7, 7 (>8)	Cryoprobes (3 mm in diameter) were placed percutaneously with a transperineal approach. Cryoprobe placement and freezing were monitored using the transrectal ultrasound	% positive biopsy	16%
			Initial PSA ng/ml in A stage	9.7
			Post treatment Mean PSA ng/ml	0.73-1.7
			Urethrorectal fistula	0.4%
			Tissue sloughing	9.8%
			Urethral stricture	2.2%
			Bladder outlet obstruction	3%
			Incontinence	4%
			Perineal pain	0.4%
			Urinary tract infection	2.2%
			Epididymitis	1.6%
			Sepsis	0.7%
			Urethral obstruction	2%
Coogan, 1995 ²⁵ Non controlled clinical trial	95 percutaneous cryoablations of the prostate on 87 patients with prostate cancer, mean age 65.4, mean PSA 12.60 ng/ml, mean Gleason score 6.03, median followup 12 months	Cryoprobes (3 mm in diameter) were placed percutaneously with a transperineal approach. Cryoprobe placement and freezing were monitored using the transrectal ultrasound. Mean operative time was 129 minutes, mean length of stay 16 days	% positive biopsy	16-38%
			Mean PSA ng/ml	1.58-3.22
			T1	3.55
			T2	1.9
			Urethrorectal fistula	1%
			Tissue sloughing	10%
			Urethral stricture	1%
			Bladder outlet obstruction	6%
			Incontinence	3.5%
			Impotence	47%
			Perineal pain	1%
			Urinary tract infection	4%
			Urethral obstruction	2%
Cox, 1995 ²⁶ Case series	Retrospective review of the charts of 63 patients (69 procedures) performed in a single center	Cryoprobes (3 mm in diameter) were placed percutaneously with a transperineal approach. Cryoprobe placement and freezing were monitored using the transrectal ultrasound	Urethrorectal fistula	3%
			Tissue sloughing	19%
			Urethral stricture	3%
			Bladder outlet obstruction	29%
			Incontinence	27%
			Perineal pain	11%
			Sepsis	3%
			Urethral obstruction	13%
			Total complications	59%
			Number of operations	43%
			Transient ischemic attack	2%
			Cerebrovascular accident	2%

Table C8. Outcomes after cryosurgical prostatectomy in patients with localized prostate cancer (continued)

Reference Design	Population Followup Definition of Outcome	Treatment	Outcome	Occurrence
Donnelly, 2002 ²⁷ Prospective pilot noncontrolled clinical trial	76 consecutive patients with adenocarcinoma of prostate mean age 65 years, 12% with T >2, mean PSA ng/ml 13, 56% Gleason ≥7, followup 50 months. Treatment failure: PSA > 1 ng/ml	Multiple percutaneous cryoprobes (5) were placed under TRUS guidance percutaneously and transperineally into the prostate	Progression free survival % positive biopsy Mean PSA ng/ml Sloughing Incontinence Testicular abscess	60-75% 1.4% 0.3-0.9 3 (3.9%) 1 (1.3%) 1 (1.3%)
Ellis, 2002 ²⁸ Case series	75 patients with localized prostate cancer, 21% with T >2, mean PSA ng/ml 8.5, 55% Gleason ≥7	Multiple percutaneous cryoprobes (6) were placed with Cryocare System, (Endocare, Inc., Irvine, CA), a cryosurgical device with 8 cryoprobe ports and an integrated temperature monitoring system	Progression free survival Mean PSA ng/ml Tissue sloughing Incontinence Impotence	84% 0-0.23 6.7% 5.5% 82.4%
Koppie, 1999 ²⁹ Case series	176 patients with clinically localized (stages T1 to T4) prostate cancer, 35.8% with T >2, mean PSA ng/ml 18.4, 20% Gleason ≥7; 57% received neoadjuvant androgen deprivation; Treatment failure: PSA >0.5 ng/ml and increased by more than 0.2 ng/ml on 2 consecutive occasions. Mean followup 30.8 months	The prostate was frozen with a multiprobe cryosurgical device. 5 probes were placed with ultrasound monitoring	Progression free survival in T1-2 At 1 year At 3 years	 82% 60%

Table C8. Outcomes after cryosurgical prostatectomy in patients with localized prostate cancer (continued)

Reference Design	Population Followup Definition of Outcome	Treatment	Outcome	Occurrence
Long, 1998 ³⁰ Prospective pilot noncontrolled trial	145 consecutive patients with nonmetastatic prostate adenocarcinoma; Androgen deprivation was used for 3 to 8 months before the procedure in 30% of patients. 28% with T >2, mean PSA ng/ml 10, 53% Gleason ≥7, followup 60 months. Treatment failure: PSA >0.3	Multiple percutaneous cryoprobes (5-8) were placed to ablate the entire prostate with real-time transrectal ultrasound monitoring	Progression free survival	56%
			Positive biopsy	21%
			Urethrorectal fistula	1.3%
			Tissue sloughing	8.9%
			Urethral stricture	3.4%
			Bladder outlet obstruction	17.2%
			Incontinence	2%
			Impotence	88%
			Perineal pain	2.3%
			Urinary tract infection	2.3%
			Epididymitis	1.5%
			Sepsis	<1%
			Urethral obstruction	4.8%
			Total complications	17%
Number of operations	17%			
Any treatment	21%			
Shinohara, 1996 ³¹ Case series	102 patients underwent cryosurgery as definitive therapy for localized prostate cancer, 57% with T >2, mean PSA ng/ml 21.8, 54% Gleason ≥7, followup 12 months	Multiple percutaneous cryoprobes were placed to ablate the entire prostate with real-time transrectal ultrasound monitoring	Progression free survival	74%
			Urethrorectal fistula	1%
			Tissue sloughing	23%
			Bladder outlet obstruction	23%
			Incontinence	15%
			Impotence	86%
			Perineal pain	3%
			Urinary tract infection	3%
			Epididymitis	3%
			Sepsis	3%
			Urethral obstruction	4%
Shinohara, 1997 ³² Case series	134 patients underwent 147 cryosurgical ablation procedures for localized prostate cancer. 35.1% with T >2, mean PSA ng/ml 19, 46.4% Gleason ≥7 biochemical failure: PSA nadir ≥0.5 ng/ml or PSA increase ≥0.2 g, followup 6 months	Multiple percutaneous cryoprobes were placed to ablate the entire prostate with real-time transrectal ultrasound monitoring	Progression free survival	89%
			Positive biopsy	11%

Table C8. Outcomes after cryosurgical prostatectomy in patients with localized prostate cancer (continued)

Reference Design	Population Followup Definition of Outcome	Treatment	Outcome	Occurrence
Sosa, 1996 ³³ Multicenter case series	1,467 patients with prostate cancer, 5% with Gleason score >8	Multiple percutaneous cryoprobes were placed to ablate the entire prostate with real-time transrectal ultrasound monitoring	Urethrorectal fistula	1.4%
			Tissue sloughing	9.9%
			Urethral stricture	5%
			Bladder outlet obstruction	6.8%
			Incontinence	11%
			Impotence	100%
			Perineal pain	9.4%
			Urinary tract infection	9.1%
			Sepsis	2.3%
Wake, 1996 ³⁴ Noncontrolled clinical trial	104 patients with localized adenocarcinoma of the prostate, 46% with T >2, mean PSA ng/ml 11.3, 14% Gleason ≥7, followup 6 months, treatment failure: PSA >4 ng/ml positive biopsy	Multiple percutaneous cryoprobes (5) were placed under ultrasound guidance. Average hospital stay 36.6 hours	Progression free survival	96%
			Positive biopsy	25%
			Mean PSA ng/ml	1.15
			Tissue sloughing	1%
			Urethral stricture	1.9%
			Bladder outlet obstruction	21.2%
			Incontinence	7.7%
			Perineal pain	9.6%
Wieder, 1995 ³⁵ Case series	83 patients with prostate cancer, mean age 67 years, 22.9% with T >2, mean PSA ng/ml 6.5-9.6	Transrectal ultrasound-guided transperineal percutaneous cryoablation with an Accuprobe System cryosurgery instrument (3 to 6 probes)	Progression free survival	92.6%
			Positive biopsy	19.3%
			Mean PSA ng/ml	3.5
			Urethrorectal fistula	0%
			Tissue sloughing	3.8%
			Urethral stricture	2.2%
			BOO	3%
			Incontinence	4%
			Perineal pain	0.4%
			Urinary tract infection	2.2%
			Epididymitis	1.6%
			Sepsis	0.7%
			Urethral obstruction	2%
Robinson, 1999, 2002 ^{36,37} Phase 2 of noncontrolled clinical trial	75 patients with localized prostate cancer, 11-12% with T 1-2, the Functional Assessment of Cancer Treatment-Prostate	Transrectal ultrasound-guided percutaneous radical cryosurgical ablation with multiple probes and transrectal ultrasound guidance	Scores (SE) (max 28)	
			Physical well-being	26.01 (2.93)
			Social/family well-being	23.46 (4.62)
			Emotional well-being	17.92 (2.87)
			Functional well-being	24.34 (3.95)
			Relationship with doctor	7.40 (1.54) max 8

Table C9. Patient outcomes after cryosurgical treatment of localized prostate cancer (evidence from nonrandomized clinical trials and case series)

Author	Bahn ³⁸	Coogan ²⁵	Wieder ³⁵	Cox ²⁶	Cohen ²⁴	Sosa ³³	Shinohara ³¹	Wake ³⁴	Shinohara ³²	Long ³⁰	Koppie ²⁹	Bahn ²³	Donnelly ²⁷	Ellis ²⁸	Aus ²¹
Year	1994	1995	1995	1995	1996	1996	1996	1996	1997	1998	1999	2002	2002	2002	2002
Followup, months	NR	12	3	12	24	NR	12	6	6	60	30.8	68.6	50	3	58.5
Number of patients	210	95	83	63	239	1467	102	104	134*	145	176	590	76	75	54
% with T >2	NR	7.4	22.9	NR	7.9	NR	57	46	35.1	28	35.8	17.6	12	21	40.7
Mean PSA ng/ml	NR	12.6	6.5-9.6	NR	9.7		21.8	11.3	19	10	18.4	NR	13	8.5	26
% Gleason ≥7	NR	NR	NR	NR	7 (>8)	5(>8)	54	14	46.4	53	20	58.5	56	55	37.04
Outcomes in patients with localized PC															
Progression free survival, %	NR	NR	92.6	NR	NR	NR	74	96	89	56	60	89-100	60-75	84	38.9
% positive biopsy	NR	16-38	19.3	NR	16	NR	NR	25	11	21	NR	13	1.4	NR	NR
Mean PSA ng/ml		1.58-3.22	3.5	NR	0.73-1.7	NR	NR	1.15	NR	NR	NR	NR	0.3-0.9	0-0.23	NR
% Complications															
Urethrorectal fistula	2.4	1	0	3	0.4	1.4	1	0	NR	1.3	NR	<0.1	NR	0	1.9
Tissue sloughing	NR	10	3.8	19	9.8	9.9	23	1	NR	8.9	NR	NR	NR	6.7	14.8
Urethral stricture	NR	1	2.2	3	2.2	5	NR	1.9	NR	3.4	NR	NR	NR	NR	11.1
BOO	3	6	3	29	3	6.8	23	21.2	NR	17.2	NR	NR	NR	NR	NR
Incontinence	9	3.5	4	27	4	11	15	7.7	NR	2	NR	4.3	NR	5.5	18.5
Impotence	40	47	NR	NR	NR	100	86	NR	NR	88	NR	94.9	NR	82.4	72.2
Perineal pain	NR	1	0.4	11	0.4	9.4	3	9.6	NR	2.3	NR	NR	NR	NR	NR
Urinary tract infection	NR	4	2.2	NR	2.2	9.1	3	NR	NR	2.3	NR	NR	NR	NR	33.3
Epididymitis	NR	0	1.6	NR	1.6	NR	3	NR	NR	1.5	NR	NR	NR	NR	NR
Sepsis	NR	0	0.7	3	0.7	2.3	3	NR	NR	<1	NR	NR	NR	NR	NR
Urethral obstruction	NR	2	2	13	2	NR	4	NR	NR	4.8	NR	NR	NR	NR	NR
Total complications	14	NR	NR	59	NR	NR	NR	NR	NR	17	NR	NR	NR	NR	NR
Number of operations	NR	NR	NR	43	NR	NR	NR	NR	NR	17	NR	NR	NR	NR	NR
Any treatment (n)	NR	NR	NR	NR	NR	NR	NR	NR	NR	21	NR	NR	NR	NR	NR

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* Probably same patients
 NR = not reported
 BOO = Bladder outlet obstruction

Table C10. Comparative effectiveness of extraperitoneal versus transperitoneal laparoscopic prostatectomy in patients with localized prostate cancer (adapted from the systematic review by Rassweiler et al)

Author	Population	Treatment	N	OR-Time (Minutes)	Complication (%)	Reintervention (%)	Transfusion (%)	Catheter Time (d)	Positive Margins (%)		
Hoznek, 2003 ³⁹ Case series Historical controls	A	B	Total	40							
	Age (years)	63	67	A-transperiton	20	224	Not reported	5	15	5.3	15
	Mean PSA (ng/ml)	9.5	11.7	B-extraperiton	20	170	7.3		10	4.2	25
	Gleason score	5.5	6.3								
	T1a	1	0								
	T1b	0	0								
	T1c	15	14								
	T2a	3	4								
T2b	1	2									
Cathelineau, 2004 ⁴⁰ Case series Historical controls	A	B	Total	200							
	Age	63	61	A-transperiton	100	173	23.8		4	6.2	26.2
	PSA	8.9	10	B-extraperiton	100	163	16.7		3	6	15.9
	T1	68	72								
	T2	32	27								
T3	0	1									
Ruiz, 2004 ⁴¹ Case series Historical controls	A	B	Total	330							
	Age	64.1	63	A-transperiton	165	248	Not reported	Not reported	1.2	5.1	23
	T1a-b	8	5	B-extraperiton	165	220	Not reported	Not reported	5.4	6.6	Not reported
	T1c	110	106								
	T2a	42	50								
	T2b	5	4								
	Mean PSA (ng/ml)	10.8	9.9								
	Gleason score	5.7	6.2								
	2-4	33	17								
	5-6	95	84								
	7	28	53								
8-9	9	11									
Erdogru, 2004 ⁴² Case series Match-paired controls	B	A	Total	106							
	Age	63	62.9	A-transperiton	53	187	24.6	1.8	13	7	20.7
	PSA	7	7.6	B-extraperiton	53	191	11.8	-	16	7	22.6
	T stage										
	2a	12	13								
	2b	21	20								
	2c	7	8								
	3a	11	10								
	3b	2	2								
	Gleason score	6	6.1								

Table C10. Comparative effectiveness of extraperitoneal versus transperitoneal laparoscopic prostatectomy in patients with localized prostate cancer (adapted from the systematic review by Rassweiler et al) (continued)

Author	Population		Treatment	N	OR-Time (Minutes)	Complication (%)	Reintervention (%)	Transfusion (%)	Catheter Time (d)	Positive Margins (%)	
Brown, 2005 ⁴³		A	B	Total	156						
Case series	Age (years)	58	56	A-transperiton	122	197	10.7	Not reported	3	Not reported	24
Historical controls	T1c	103	23	B-extraperiton	34	191	11.8	Not reported	–	Not reported	21
	T2	19	11								
	Gleason score 6	104	25								
	Gleason score >7	18	9								
	Gleason score (mean)	15	14.9								
Remzi, 2005 ⁴⁴		B	A	Total	80						
Case series	Age (years)	59	61	A-transperiton	39	279	20	7.7	Not reported	Not reported	25.6
	PSA (ng/ml)	8.1	5.5	B-extraperiton	41	217	37	2.4	Not reported	Not reported	19.5
	Gleason score	5.5	5.1								

Table C11. Comparative effectiveness of laparoscopic versus retropubic radical prostatectomy (adapted from the systematic review by Rassweiler et al)

Author	Population	Treatment	Sample Size	OR-Time (minutes)	Complication (%)	Reintervention (%)	Analgesics (mg)	Blood Loss (cc)	Transfusion (%)	
Guilloneau, 2000 ⁴⁵ Case series		LRP RRP	Total	220						
	PSA ng/ml	11.2 11	RRP	100	135	Not reported	Not reported	850	31	
	Gleason score	6 6	LRP	120	239	7.3	2.5	402	10	
	Stage									
	pT2	85 107								
	pT3a	8 7								
	pT3b	7 6								
Salomon, 2002 ⁴⁶ Case series		RRP PRP LRP	Total	401						
	Age	65 64.6 64.1	RRP	219	197	23.8	Not reported	Not reported	26.2	
	PSA	21 13.2 11.6	PRP	219	178	16.7	Not reported	Not reported	15.9	
	Gleason Score	5.7 5.7 5.7	LRP	219	285	18.1	Not reported	Not reported	2.9	
Rassweiler, 2003 ⁴⁷ Case series		RRP LRP LRP	Total	657						
		Early Later	RRP	219	196	19.1	6.8	50.8a	1,550	55.7
	Age	65 64 64	LRP early	219	288	13.9	4.2	33.8	1,100	30.1
	pT1	5 5 1	LRP late	219	218	6.1	2	30.1	800	9.6
	pT2a	55 43 39								
	pT2b	40 73 103								
	pT3a	72 53 49								
	pT3b	21 35 22								
	pT4	24 10 5								
	Gleason score	7 6 6								
	PSA (ng./ml)	12 14.6 10.6								
Bhayani, 2003 ⁴⁸ Case series		RRP LRP	Total	60						
	Age (years)	60.5 57.4	RRP	24	168	20.8	12.5	45	1,473	Not reported
	PSA (ng/ml)	8.6 6.74	LRP	36	348	21.2	6	53c	533	Not reported
	Gleason score	6.13 6.06								
	T1a	1 0								
	T1c	14 21								
	T2a	8 11								
T2b	1 1									
Roumeguere, 2003 ⁴⁹ Nonrandomized clinical trial		RRP LRP	Total	162						
	Age	64 62.5	RRP	77	168	24.6	7.8	Not reported	1514	Not reported
	PSA (ng/ml)	11 8.6	ELRP	85	288	11.8	3.5	Not reported	522	Not reported
	Gleason score	5.4 5.4								
Artibani, 2003 ⁵⁰ Case series		RRP LRP	Total	121						
	Age	64.3 63	RRP	50	105	20	4	Not reported	Not reported	34
	PSA (ng/ml)	11 16	LRP	71	180	37	4.2	Not reported	Not reported	63
	T1b	4 1								
	T1c	26 20								

Table C11. Comparative effectiveness of laparoscopic versus retropubic radical prostatectomy (adapted from the systematic review by Rassweiler et al) (continued)

Author	Population		Treatment	Sample Size	OR-Time (minutes)	Complication (%)	Reintervention (%)	Analgesics (mg)	Blood Loss (cc)	Transfusion (%)	
	T2a	15	34								
	T2b	4	10								
	T3	1	6								
	Gleason score	5.7	5.8								
Brown, 2004 ⁵¹		LRP	RRP	Total	120						
Case series	Age	59	59	RRP	60	Not reported	18.3	3.3	Not reported	1355	52
	PSA (ng/ml)	6.4	5.6	LRP	60	330	25	3.3	Not reported	317	1.7
	T1a/b	0	1								
	T1c	47	45								
	T2a	13	11								
	T2b	0	3								
Fornara, 2004 ⁵²				Total	64						
Nonrandomized clinical trial				RRP	32	140	9.3	Not reported	35	550	17
				ELRP	32	220	3.1	Not reported	33	200	6
Remzi, 2005 ⁴⁴		LRP	RRP	Total	121						
Case series	Age (years)	59	60	RRP	41	195	Not reported	7.3	300	385	Not reported
	PSA (ng/ml)	8.1	6.9	LRP	39	279	Not reported	7.7	290	290	Not reported
	Gleason score	5.5	4.7	ELRP	41	217	Not reported	2.4	189	189	Not reported
Keller, 2005 ^{53,54}	PSA >10 ng/ml			Total	150						
Nonrandomized clinical trial	Gleason score >5			RRP	50	150	Not reported	Not reported	Not reported	739	4
				PRP	50	86	Not reported	Not reported	Not reported	269	0
				LRP	50	249	Not reported	Not reported	Not reported	322	16

Table C12. Comparative effectiveness of laparoscopic, retropubic, and perineal radical prostatectomy (adapted from the systematic review by Rassweiler et al)

Author	Population	Treatment	N	Continence (1 year) (%)	Potency Bilat Ns. (%)	Positive Margins (%)	PSA Relapse (%)	Overall Survival (%)	
Salomon, 2002 ⁴⁶ Case series		RRP PRP LRP	Total	401					
	Age	65 64.6 64.1	RRP	219	Not reported	Not reported	31.7	Not reported	
	PSA	21 13.2 11.6	PRP	219	Not reported	Not reported	18.5	Not reported	
	Gleason Score	5.7 5.7 5.7	LRP	219	Not reported	Not reported	28.5	Not reported	
Rassweiler, 2003 ⁴⁷ Case series		RRP LRP LRP	Total	657					
		Early Later	RRP	219	89.9	Not reported	28.7	17.4	96.6
	Age	65 64 64	LRP early	219	90.3	Not reported	21	13.2	98.6
	pT1	5 5 1	LRP late	219	91.7	Not reported	23.7	Not reported	Not reported
	pT2a	55 43 39							
	pT2b	40 73 103							
	pT3a	72 53 49							
	pT3b	21 35 22							
	pT4	24 10 5							
	Gleason score	7 6 6							
	PSA (ng/ml)	12 14.6 10.6							
	Anastasidis, 2003 ⁵⁵		RRP LRP	Total	300				
Age		65 64.1	RRP	70	66.7	44%	Not reported	Not reported	Not reported
PSA (ng/mL)		11 10.7	LRP	230	71.6	53%	Not reported	Not reported	Not reported
Gleason score		6 5.8							
T1a-b		2 10							
T1c		50 156							
T2a		17 58							
T2b		1 6							
Gleason score		7 6.7							
Roumequere, 2003 ⁴⁹ Nonrandomized clinical trial		RRP LRP	Total	162					
	Age	64 62.5	RRP	77	83.9	54.5	40.2	6.9	Not reported
	PSA (ng/ml)	11 8.6	ELRP	85	80.7	65.3	25.8	8.6	Not reported
	Gleason score	5.4 5.4							
Artibani, 2003 ⁵⁰ Case series		RRP LRP	Total	121					
	Age	64.3 63	RRP	50	78.5	10	24	11	Not reported
	PSA (ng/ml)	11 16	LRP	71	60	8	30	19	Not reported
	T1b	4 1							
	T1c	26 20							
	T2a	15 34							
	T2b	4 10							
	T3	1 6							
Gleason score	5.7 5.8								

Table C12. Comparative effectiveness of laparoscopic, retropubic, and perineal radical prostatectomy (adapted from the systematic review by Rassweiler et al) (continued)

Author	Population	Treatment	N	Continen- (1 year) (%)	Potency Bilat Ns. (%)	Positive Margins (%)	PSA Relapse (%)	Overall Survival (%)
Remzi, 2005 ⁴⁴		LRP RRP Total	121					
Case series	Age (years)	59 60 RRP	41	Not reported	Not reported	19.5	Not reported	Not reported
	PSA (ng/ml)	8.1 6.9 LRP	39	Not reported	Not reported	25.6	Not reported	Not reported
	Gleason score	5.5 4.7 ELRP	41	Not reported	Not reported	19.5	Not reported	Not reported
Keller, 2005 ^{53,54}	PSA >10 ng/ml	Total	150					
Nonrandomized clinical trial	Gleason score > 5	RRP	50	88	Not reported	20	Not reported	Not reported
		PRP	50	90	Not reported	11.7	Not reported	Not reported
		LRP	50	50	Not reported	16	Not reported	Not reported

Table C13. Perioperative and pathological parameters and complication rates after three surgical treatments of prostate cancer: robotic assisted, laparoscopic, and open radical retropubic prostatectomy, pooled estimated from 24 observations

Outcomes	Robotic Assisted RP	LRP	Open RP
Installation time (minutes)	32		
Operative time (minutes)	222	225	182
Mean EBL (ml)	231	505	727
Blood transfusion (%)	3.9	8.4	24
Conversion/abortion (%)	1.1	1.4	
Catheter time (days)	8.1	6.1	7-21
Positive margins T2 (%)	77.5	72.4	64
Positive margins T3 (%)	21.6	26.5	32.2
Total positive surgical margins (%)	15	19.9	24.1
Pathological stage 2/positive surgical margins (%)	8.5	13.8	17.5
Overall complications (%)	8.3	16.8	10.3
Minor complications (%)	4.6	13	6.3
Major complications (%)	3.8	4.9	4

Figure C3. Comparative studies of LRP vs. RRP; operative data (from the systematic review of nonrandomized clinical trials and case series by Rassweiler et al)

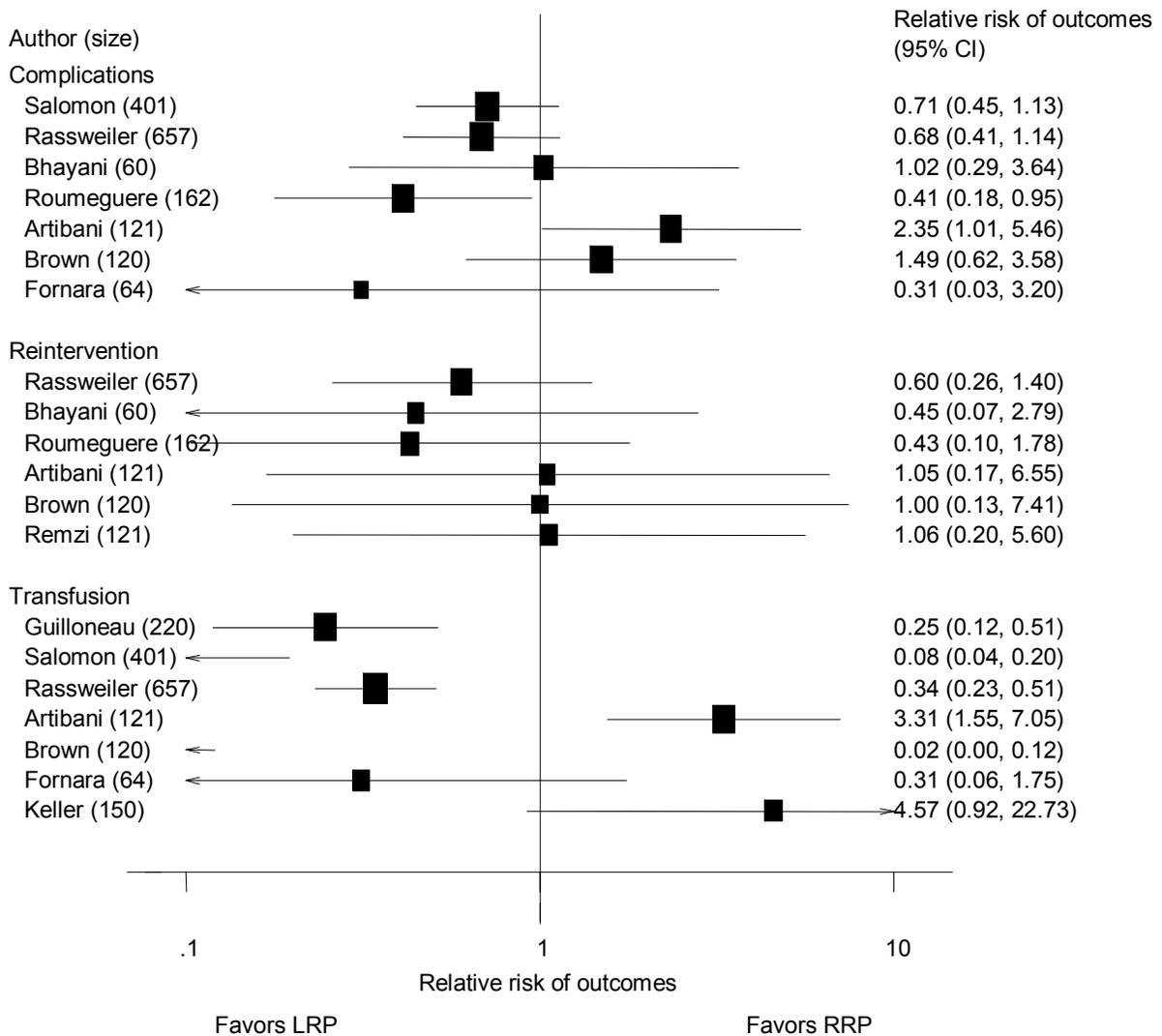


Figure C4. Comparative studies of transperitoneal vs. extraperitoneal radical prostatectomy; operative data (from the systematic review of nonrandomized clinical trials and case series by Rassweiler et al)

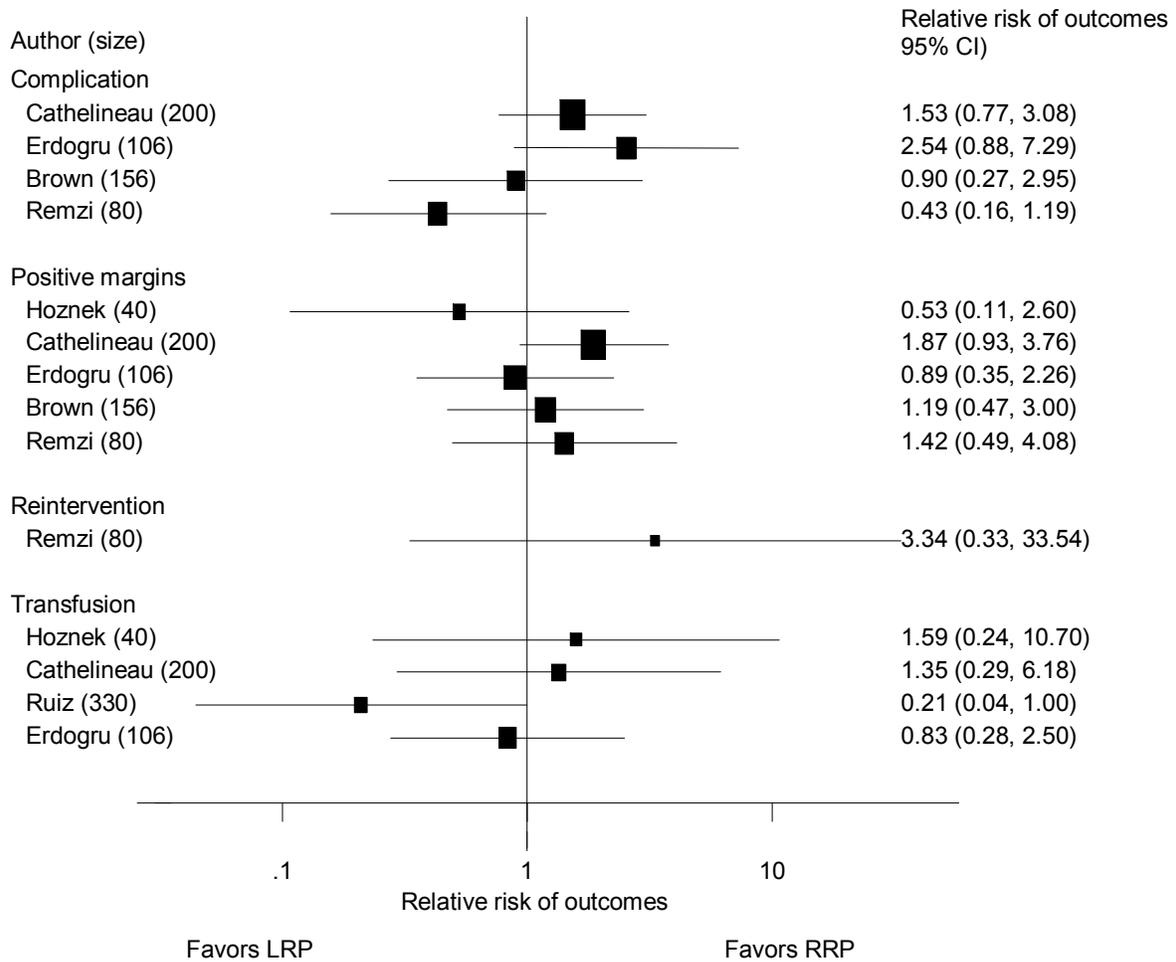


Table C14. Outcomes after laparoscopic extraperitoneal, transperitoneal, robot assisted, and radical retropubic prostatectomy (from systematic review by Tooher et al)⁵⁶

Outcome (Number of Studies)	Effect Size
% Conversions to open procedure (12)	0–14 (median 2)
% Total complications	
Transperitoneal LRP vs. RRP (6)	0–25 (median 17) vs. 8–25 (median 19)
Extraperitoneal endoscopic RP vs. RRP (3)	11–37 (median 14) vs. 8–30 (median 20)
Robot assisted RP vs. RRP (2)	5 + 7 vs. 20 + 10
Blood loss (ml)	
Transperitoneal LRP vs. RRP (5)	317–1,100 (median of means 800) vs. 1,325–1,550 (median of means 1,400)
Extraperitoneal endoscopic RP vs. RRP (2)	795 vs. 829, 522 vs. 1,514
Robot assisted RP vs. RRP (3)	103–382 (median of means 153), 418–1,330 (median of means 910)
% Transfusions	
Transperitoneal LRP vs. RRP (5)	0–18 (median 2) vs. 10–56 (median 26)
Extraperitoneal endoscopic RP vs. RRP (1)	34 vs. 64
Robot assisted RP vs. RRP (3)	0–28 (median 0) vs. 2–67 (median 38)
Operative time (minutes)	
Transperitoneal LRP or extraperitoneal endoscopic RP vs. RRP (10)	180–400 (median of means 288) vs. 105–235 (median of means 168)
Robot assisted RP vs. RRP (4)	160–368 (median of means 231) vs. 163–242 (median of means 214)
Length of stay (days)	
Transperitoneal LRP vs. RRP (8)	2–12 (median of means 5) vs. 3–16 (median of means 7)
Extraperitoneal endoscopic RP vs. RRP (1)	7.2 vs. 10.1
Robot assisted RP vs. RRP (3)	1.1–2.0 (median of means 1.2) vs. 2.2–3.5 (median of means 2.7)
Catheterization (days)	
Transperitoneal LRP vs. RRP (5)	6.5–14 (median of means 7) vs. 12–19 (median of means 15)
Extraperitoneal endoscopic RP vs. RRP (2)	6–11.8 (median of means 8) vs. 8.4–15 (median of means 14)
Robot assisted RP vs. RRP (3)	6.3–7 (median of means 7) vs. 9–15.8 (median of means 13)
% Positive margins	
Transperitoneal LRP vs. RRP (8)	11–50 (median 23) vs. 20–34 (median 29)
Extraperitoneal endoscopic RP vs. RRP (3)	16–30 (median 26) vs. 15–40 (median 24)
Robot assisted RP vs. RRP (4)	6–26 (median 16) vs. 4–29 (median 20)
% Recurrence-free survival	
Transperitoneal LRP vs. RRP (2)	84 + 99 vs. 75 + 97
Extraperitoneal endoscopic RP vs. RRP (2)	91 + 81 vs. 93 + 89
Robot assisted RP vs. RRP (2)	92 + 95 vs. 85 + 95
Continence (% pad free)	
Transperitoneal LRP vs. RRP (3)	60–90 (median 80) vs. 67–90 (median 89)
Extraperitoneal endoscopic RP vs. RRP (3)	79–90 (median 81) vs. 60–88 (median 83.9)
Robot assisted RP vs. RRP (3)	76–90 (median 78) vs. 68–83 (median 75)
% Potency	
Transperitoneal LRP vs. RRP (1)	41 vs. 30
Extraperitoneal endoscopic RP vs. RRP (2)	9 + 65 vs. 10 + 55
Robot assisted RP vs. RRP (2)	71 + 90 vs. 59 + 40

* PSA 0.2 m/l or greater on more than 1 occasion

LRP= laparoscopic radical prostatectomy

RRP= retropubic radical prostatectomy

Table C15. Comparative effectiveness of robotic assisted laparoscopic radical prostatectomy

Author, Sample	Active vs. Control Treatment	Outcome	Outcome Rate After Active Treatment	Outcome Rate After Active Control Treatment	p
Ahlering, 2004 ⁵⁷ The first 140 consecutive robot-assisted radical prostatectomies, pT2a - T2b 59 men <66 years of age with Sexual Health Inventory in Men (SHIM) score of 22 to 25 were treated with cautery-free technique (CFT) to preserve the neurovascular bundles (NVB) during robotic laparoscopic radical prostatectomy	Cases 51–140, define the prostatic apex precisely vs. cases 1–50	Positive margins	3	9	0.003
Ahlering, 2005 ⁵⁸ 59 men <66 years of age with Sexual Health Inventory in Men (SHIM) score of 22 to 25 were treated with cautery-free technique (CFT) to preserve the neurovascular bundles (NVB) during robotic laparoscopic radical prostatectomy	Preservation of the NVB with CFT vs. traditional dissection using bipolar cautery	Erection adequate for vaginal penetration at 3 months	10	3	0.003
		Zero penile fullness at 3 months	2	15	
Ahlering, 2004 ⁵⁹ 60 standard RPs and 60 robot-assisted laparoscopic RPs performed by one surgeon	Robotic assisted laparoscopic RP vs. RP	Positive margins	2	4	
Badani, 2005 ⁶⁰ Twenty-eight anastomotic drills performed randomly in a blinded fashion	Three-dimensional (3D) suturing frills vs. two-dimensional (2D) suturing frills	Operative time per drill	8.5 minutes (range 4.7-12.8 minutes)	13.1 minutes (6.9-21.9)	<0.001
		Major errors in performances	2	5	
Farnham, 2006 ⁶¹ 279 patients with localized PC made the decision which surgical approach to use	Robotic assisted laparoscopic RP vs. RP	Intraoperative blood loss	191	664	< 0.001
		Transfusion of blood products	1	3	
Hu, 2006 ⁶² 358 patients, 4 with T3 after LRP and 322 after RAP	Robotic assisted laparoscopic RP vs. laparoscopic RP	Estimated blood loss	250 (50–1,600)	200 (0–1,500)	
		Operative time	3.1 (1.9–8.8)	4.1 (2.5–12.8)	
		Urological complications	40	77	
		Bowel complications	11	34	
		Vascular complications	4	7	
Menon, 2002 ⁶³ 48 laparoscopic radical prostatectomies and 50 robot assisted prostatectomies	Robotic assisted laparoscopic RP vs. laparoscopic RP	Mean mins. operating time (SE)	274	258	0.4
		Mean ml. estimated blood loss (SE)	256	391	0.013

Table C15. Comparative effectiveness of robotic assisted laparoscopic radical prostatectomy (continued)

Author, Sample	Active vs. Control Treatment	Outcome	Outcome Rate After Active Treatment	Outcome Rate After Active Control Treatment	p
Menon, 2002 ⁵⁴ Prospective nonrandomized comparison of RRP and RAP in 60 patients with clinically localized prostate cancer who elected surgical treatment.	Robotic assisted laparoscopic RP vs. RP	Mean gm/dl hemoglobin decrease (SE)	2.6	3	0.17
		Mean % hematocrit decrease (SE)	17.2	20.1	0.11
		No. intraop. blood transfusion (%)	0	1	>0.99
		No. conversion to open surgery (%)	0	1	>0.99
		No. discharge home less than 24 hours (%)	32	26	0.13
		No. pos. margins	5	5	
		Operative time (hr)	4.8 (4–7)	2.3 (1.5–5)	
		EBL (mL)	329 (75–1050)	970 (400–2200)	
		Blood transfusion (%)	7	30	
		Mean postoperative pain score (range)	4 (1–9)	7 (4–10)	<0.05
		Hemoglobin drop (g/dL)	1.2 (0.1–2)	4.4 (0.5–4.8)	<0.05
		Mean hospital stay (hr)	36 (23–96)	56 (48–96)	NS
		Discharged within 24 hr (%)	63	0	<0.001
		Mean duration of catheterization (days)	10.7 (6–18)	13.7 (7–18)	NS
		Gleason score	6.9 (2–9)	6.6 (2–9)	NS
		Node status (%)	0	0	NS
		Margin positivity (%)	26	29	NS
		Focal	12	14	NS
		Extensive	14	15	NS
		Seminal vesicle positivity (%)	10	10	NS
		Intraoperative bleeding (>1,000 mL)	1	5	<0.05
Conversion	1		NS		
Rectal injuries	0	1	NS		
Postoperative urinary retention	1	1	NS		
Postoperative ileus	3	3	NS		
Exaggeration of arthritis	1	0	NS		
Wound dehiscence	1	1	NS		
Tewari, 2003 ⁵⁵ 100 patients undergoing RRP and 200	Robotic assisted laparoscopic RP vs. RP	Catheterization, days	7 (1–18)	15.8 (7–28)	< 0.05
		Collow-up, days	236	556	< 0.05

Table C15. Comparative effectiveness of robotic assisted laparoscopic radical prostatectomy (continued)

Author, Sample	Active vs. Control Treatment	Outcome	Outcome Rate After Active Treatment	Outcome Rate After Active Control Treatment	p
undergoing VIP, 5.5% with T3A		Undetectable PSA, %	92	85	NS
		% cancer in specimen	19 (1–80)	18.3 (5–90)	NS
		Complications	5	20	< 0.05
		Time of 50% return of erection	180 days	440 days	
		Using sildenafil	42%	65%	
Menon, 2004 ⁶⁶ 1,100 cases of robotic radical prostatectomy in patients with localized prostate cancer and a life expectancy of over 10 year	Robotic assisted laparoscopic RP vs. RP	Operating room time	Crude odds ratio 0.91	163 min	
		Estimated blood loss	0.1	910 mL	<0.05
		Positive margins	1	23%	
		Complications	0.33	15%	<0.05
		Catheterization time	0.44	15.8 d	<0.05
		Hospital stay > 24 hours	0.07	100%	<0.05
		Postoperative pain score (0–10)	0.45	7	<0.05
		Median time to continence (days)	0.28	160	<0.05
		Median time to erection (days)	0.4	440	<0.05
		Median time to intercourse(days)	0.5	>700	<0.05
		Detectable prostate specific	0.5	15%	
		Rozet, 2007 ⁶⁷ 133 consecutive patients who underwent extraperitoneal robot assisted radical prostatectomy compared to 133 match-paired patients treated with a pure extraperitoneal laparoscopic approach, 0.8% with T3	Extraperitoneal robotic assisted laparoscopic RP vs. extraperitoneal laparoscopic RP	Mean ml blood loss	609 (100-3,000)
Mean operative mins	166 (90-300)			160 (90-270)	0.09
% transfusion rate	3			9.8	0.02
Hospital stay (days)	5.4 (3-26)			4.9 (3-20)	0.21
Bladder catheter (days)	9.2 (6-29)			9.0 (7-31)	0.56
Pos surgical margins	19.5			15.8	0.42
Complications	19.4			9.1	0.01
Anastomotic leakage	0.8			0.8	
Wound abscess	0.8			0	
Infected pelvic hematoma	2.2			1.5	
Urinary infection	4.4			0.8	
Postop bleeding	4.4			0.8	
Retention	0.8			2.2	
Anastomotic leakage	0.8			0.8	
Postop bleeding	2.2			0	
Urinary sepsis	1.5			1.5	

Table C15. Comparative effectiveness of robotic assisted laparoscopic radical prostatectomy (continued)

Author, Sample	Active vs. Control Treatment	Outcome	Outcome Rate After Active Treatment	Outcome Rate After Active Control Treatment	p		
Patel, 2007 ⁶⁸ 500 robotically assisted laparoscopic radical prostatectomies, 22% with >T2	Robotic assisted laparoscopic RP	Pulmonary embolism	0	0.8			
		Renal insufficiency	1.5	0			
		Pos surgical margins	9.4				
		Mean Operative duration, min	130				
		Mean EBL, mL	50				
		Conversion rate, %	0.6				
		% blood transfusion	0				
		No. complications during RALP	2				
		Mean haematocrit change, %	3.1				
		% of patients requiring no narcotics	85				
		Mean catheter duration, days	6.9				
		% discharged home on day 1	97				
		Complete continence, %, at 3 months	89				
		Complete continence, %, at 6 months	95				
		% undetectable PSA level at 9.7month	95				
		Zorn, 2007 ⁶⁹ 300 consecutive cases of robotic-assisted laparoscopic radical prostatectomy with selective use of interfascial nerve preservation, all with T1-2	Robotic assisted laparoscopic RP with selective use of interfascial nerve preservation	Operative time (min)	282 (143–540)		
				Estimated blood loss (ml)	273 (25–1500)		
Transfused (%)	5 (1.7)						
Hospital stay (days)	1.4 (1–6)						
Length of foley catheter	5.9 (4–26)						
Myocardial infarction	0.6						
Thromboembolic event	0.6						
Hemorrhage	1						
Rectal injury							
Ureteral injury							
Lymphocele	0.6						
Anastamotic leak	1.4						
Bladder neck contracture	1.4						
Wound infection/hernia	2						
Femoral nerve palsy	1.4						
Positive surgical margins	20.9						

Table C15. Comparative effectiveness of robotic assisted laparoscopic radical prostatectomy (continued)

Author, Sample	Active vs. Control Treatment	Outcome	Outcome Rate After Active Treatment	Outcome Rate After Active Control Treatment	p
		Intra-operative complication	2.3		
		Subjective continence at 12 months	90.20		
		Subjective potency at 12 months	80.4		
		Pathologic-T3 Positive surgical margins with ipsilateral interfascial nerve preservation	73		
		Pathologic-T3 Positive surgical margins without ipsilateral interfascial nerve preservation	33		
Mikhail, 2006 ⁷⁰	Robotic assisted laparoscopic RP	Operative time	200-520		
nonrandomized prospective trial of initial 100 patients who underwent robotic-assisted laparoscopic radical prostatectomy, all with T1-2		Estimated blood loss (mL)	25-1500		
		Length of hospitalization (days)	1-6		
		Length of foley catheterization	4-26		
		Positive margin rate	16		
		Postoperative bleed	1		
		Postoperative hematuria	1		
		Bladder neck contracture	2		
		Anastomotic leak	3		
		Lymphocele	2		
		Wound infection	2		
		Pulmonary embolus	1		
		Transient mild CHF	1		
		Wound dehiscence (after altercation)	1		
		Hand numbness	1		
		Postoperative ileus	1		
		Incisional hernia	1		
		Total complications	13		
		Subjective continence at 12 months	89		
		Subjective potency, unilateral at 12 months	68		
Rand 36-item health survey					

Table C15. Comparative effectiveness of robotic assisted laparoscopic radical prostatectomy (continued)

Author, Sample	Active vs. Control Treatment	Outcome	Outcome Rate After Active Treatment	Outcome Rate After Active Control Treatment	p
		Subjective potency, bilateral at 12 months	79		
		Subjective potency, overall at 12 months	75		
		Urinary function at 12 months	74.8 ± 24.9		NS compared to baseline
		Urinary bother at 12 months	82.7 ± 27.3		NS compared to baseline
		Sexual function, unilateral at 12 months	52.9 ± 29.0		NS compared to baseline
		Sexual function, bilateral at 12 months	60.1 ± 23.6		NS compared to baseline
		Sexual function, overall at 12 months	57.3 ± 25.8		NS compared to baseline
Tseng, 2006 ⁷¹ Case series of 90 patients undergoing robot-assisted laparoscopic prostatectomy, 8.9% with >T2 median followup 9.5 months Expanded Prostate Cancer Index Composite questionnaire	Robotic assisted laparoscopic RP	Urinary, function at 9.5 months	80.8 ± 19.6		
		Urinary, bother at 9.5 months	78.6 ± 21.2		
		Urinary, incontinence at 9.5 months	68.8 ± 31.9		
		Urinary, Irritative/obstructive at 9.5 months	87.0 ± 13.6		
		Urinary, summary score at 9.5 months	79.5 ± 19.6		
		Sexual, function at 9.5 months	20.5 ± 17.2		
		Sexual, bother at 9.5 months	32.2 ± 27.7		
		Sexual, summary score at 9.5 months	24.1 ± 19.1		
		Bowel, function at 9.5 months	94.5 ± 7.1		
		Bowel, bother at 9.5 months	94.6 ± 10.0		
		Bowel, summary score at 9.5 months	94.5 ± 8.0		

Table C15. Comparative effectiveness of robotic assisted laparoscopic radical prostatectomy (continued)

Author, Sample	Active vs. Control Treatment	Outcome	Outcome Rate After Active Treatment	Outcome Rate After Active Control Treatment	p
		Hormonal, function at 9.5 months	86.5 ± 12.5		
		Hormonal, bother at 9.5 months	89.9 ± 12.0		
		Hormonal, summary score at 9.5 months	88.4 ± 11.7		
		SF-12 component score, physical at 9.5 months	50.5 ± 10.1		
		SF-12 component score, mental at 9.5 months	53.0 ± 9.1		
		Recover to baseline urinary summary score at 12 months	76.8		
		Recover to baseline sexual summary score at 12 months	19.2		

Bold - significant at 95% confidence level difference

Table C16. Comparison of task performance of AESOP (N=10) and EndoAssist (N=10) during operative steps of laparoscopic radical prostatectomy

Outcomes	AESOP Mean ± STD	EndoAssist Mean ± STD	Difference (95% CI)	P Value
Robot setup and assembly to laparoscope	2 ± 0.8	5.3 ± 2.4	-1.85 (-2.91; -0.78)	0.001
Identification and dissection of vas deferens and seminal vesicles	33.3 ± 13.4	22.7 ± 7	0.99 (0.06; 1.93)	0.04
Development of space between Denonvilliers' fascia and rectum	9.9 ± 2.73	7.8 ± 2.6	0.79 (-0.13; 1.70)	0.09
Development of prevesical space of Retzius	8.7 ± 3.8	8.8 ± 3.6	-0.03 (-0.90; 0.85)	0.95
Dissection of prostatic apex	16.7 ± 10.3	11.4 ± 2.3	0.71 (-0.20; 1.62)	0.13
Ligation of deep dorsal vein	5.9 ± 1.8	5.8 ± 1.9	0.05 (-0.82; 0.93)	0.91
Development of lateral neurovascular bundle groove	18.7 ± 3.5	14.9 ± 7	0.69 (-0.22; 1.59)	0.21
Bladder neck transection	13.2 0 ± 3.6	12 ± 3.3	0.35 (-0.54; 1.23)	0.45
Antegrade preservation of neurovascular bundles	24 0 ± 7.5	23.1 ± 8.7	0.11 (-0.77; 0.99)	0.81
Apical transection of prostate	13.1 0 ± 5	12.7 ± 6.2	0.07 (-0.81; 0.95)	0.88
Urethrovesical anastomosis	48.9 ± 12.8	40.3 ± 13	0.67 (-0.24; 1.57)	0.15
Pelvic lymph node dissection	11.6 ± 5.6	11 ± 3.4	0.13 (-0.75; 1.01)	0.78
Specimen procurement and trocar site closure	20.9 ± 7.6	19.5 ± 5.4	0.21 (-0.67; 1.09)	0.64

AESOP = Automated Endoscope System for Optimal Positioning

Table C17. Clinical outcomes after IMRT in patients with localized prostate cancer

Author, Design	Outcomes	Rate Active, %	Rate Control, %
Kupelian, 2002 ⁷² Case series of 166 patients treated with IMRT 70 Gy in 28 fractions and 116 with 3D-CRT 78 Gy in 39 fractions % of >T2: 7% Followup: 25-32 months	Freedom of biochemical relapse: 3 consecutive rising PSA after reaching a nadir	91	88
	Freedom of biochemical relapse: reaching and maintaining PSA of ≤0.5 ng/ml	84	70
Kupelian, 2005 ⁷³ Case series of 100 patients treated with IMRT 70.0 Gy at 2.5 Gy per fraction and 310 with 3D-CRT 78 Gy at 2 Gy per fraction % of >T2: 62% Followup: 66 months	Freedom of biochemical relapse: ASTRO definition (the first documented rise in PSA)	85	78
	Freedom of biochemical relapse: nadir PSA >2 ng/ml	88	93
Zelevsky, 2006 ⁷⁴ Case series of 561 patients treated with IMRT 81.0 Gy % of >T2: 6% Followup: 84 months	Freedom of biochemical relapse: absolute nadir plus 2 ng/ml dated at the call).	85	
	Freedom of biochemical relapse in low risk patients	89	
	Distant metastases	3	
	Distant metastases in low risk patients	1	
De Meerleer, 2007 ⁷⁵ Case-series of 133 patients treated with IMRT 76 -74 Gy % of >T2: 33% Followup: 36 months	Overall survival at 5 years	96	
	Biochemical relapse-free survival as three consecutive PSA rises at 3 years	88	
	At 5 years	83	
	5 years biochemical relapse-free survival for patients:		
	low-risk	100	
	intermediate-risk	94	
	high-risk group	74	
	5 years clinical relapse-free survival	85	
	5 years clinical relapse-free survival In high-risk group, AD-naïve patients	44	
	Hazard ratio of biochemical relapse free survival in high risk	6.21 (0.96; 40.07)	
	Hazard ratio of biochemical relapse		
	Total Gleason score	1.07 (0.75; 1.53)	
	Pretreatment PSA	1.02 (0.99; 1.04)	
Risk group	3.07 (0.92; 10.3)		
Prescription dose	0.34 (0.11; 0.98)		
Use of AD	0.28 (0.10; 0.79)		
Segment outline weight adapting tool	0.41 (0.13; 1.36)		

Bold - significant at 95% confidence level difference

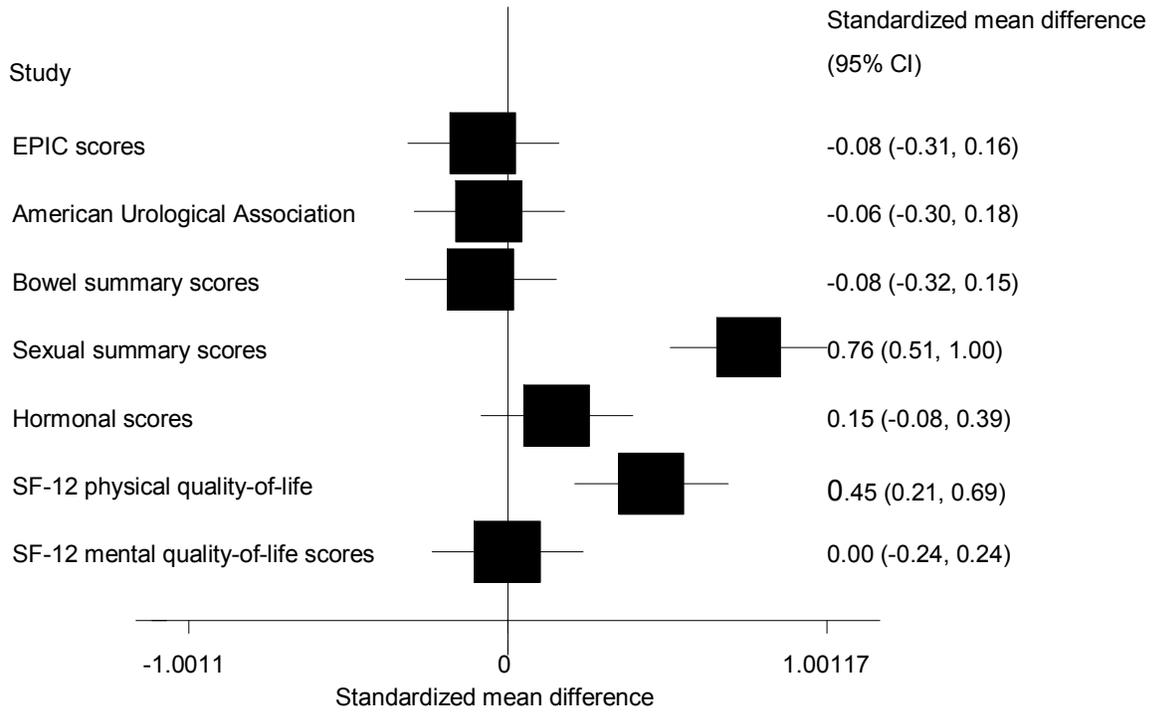
Table C18. Acute toxicity outcomes after intensity modulated radiotherapy for prostate cancer

Author, Design	Acute Toxicity Outcomes	Rate in Active Group, %	Rate in Control Group, %
Zelevsky, 2006 ⁴ Case series of 561 patients treated with IMRT 81.0 Gy % of >T2: 6% Followup: 84 months	Grade 2 rectal bleeding	1.6	
	Grade 3 rectal toxicity	0.1	
D'Amico, 2006 ⁶ Phase II clinical trial 100 patients treated with IMRT 75.6Gy+flutamide 250 mg 3 times/day % of >T2: 8% Followup: 12 months	Rectal bleeding	10	
Zelevsky 2002 ⁷ Case series of 698 patients treated with IMRT 81.0 Gy and 74 with IMRT 86.4 Gy % of >T2: 28% Followup: 29 months	Acute genitourinary toxicity Grade 1	37	46
	Acute genitourinary toxicity Grade 2	28	31
	Acute genitourinary toxicity Grade 3	0.5	0

Table C19. Late toxicity outcomes after intensity modulated radiotherapy for prostate cancer

Author, Design	Chronic Toxicity Outcomes	Rate Active, %	Rate Control, %
Kupelian, 2002 ⁷² Case series of 166 patients treated with IMRT 70 Gy in 28 fractions and 116 patients treated with 3D-CRT 78 Gy in 39 fractions. % of >T2: 7% Followup: 25-32 months	Grade 2-3 late rectal toxicity	5	12
	Actuarial Grade 3 late rectal toxicity	2	8
Kupelian, 2005 ⁷³ Case series of 100 patients treated with IMRT 70.0 Gy at 2.5 Gy per fraction and 310 patients treated with 3D-CRT 78 Gy at 2 Gy per fraction % of >T2: 62% Followup: 66 months	Actuarial Grade 2 and 3 late rectal toxicity	11	
	Actuarial Grade 3 late urinary toxicity	1	
Zelevsky 2002 ⁷⁷ Case series of 698 patients treated with IMRT 81.0 Gy and 74 with IMRT 86.4 Gy % of >T2: 28% Followup: 29 months	Late Gastrointestinal toxicity grade 2	1.5	
	Late Gastrointestinal toxicity grade 3	0.5	
Kupelian, 2002 ⁷² Case series of 166 patients treated with IMRT 70 Gy in 28 fractions and 116 patients treated with 3D-CRT 78 Gy in 39 fractions. % of >T2: 7% Followup: 25-32 months	Late urinary toxicity	2.4	1.7
Kupelian, 2005 ⁷³ Case series of 100 patients treated with IMRT 70.0 Gy at 2.5 Gy per fraction and 310 patients treated with 3D-CRT 78 Gy at 2 Gy per fraction % of >T2: 62% Followup: 6 months	Actuarial Grade 2 and 3 late urinary toxicity	8	
Zelevsky 2002 ⁷⁷ Case series of 698 patients treated with IMRT 81.0 Gy and 74 with IMRT 86.4 Gy % of >T2: 28% Followup: 29 months	Late Genitourinary toxicity grade 1	22	24
	Late Genitourinary toxicity grade 2	9	12
	Late Genitourinary toxicity grade 3	0.5	0
Zelevsky 2006 ⁷⁴ Case series of 561 patients treated with IMRT 81.0 Gy % of >T2: 6% Followup: 84 months	Late grade 2 urinary toxicities	9	
	Late grade 3 urinary toxicities	3	
	Erectile dysfunction	49	
De Meerleer, 2007 ⁷⁵ Case-series of 133 patients treated with IMRT 76 -74 Gy % of >T2: 33% Followup: 36 months	Late gastrointestinal morbidity grade 1	47	
	Late gastrointestinal morbidity grade 2	17	
	Late gastrointestinal morbidity grade 3	1	
	Late genitourinary morbidity grade 1	43	
	Late genitourinary morbidity grade 2	19	
Late genitourinary morbidity grade 3	3		

Figure C5. Quality of life measures after IMRT vs. 3D-CRT} (Kupelian, 2002)⁷²



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Table C20. Patient outcomes after high-intensity focused ultrasound therapy for localized prostate cancer

Author, Year	Gelet, 2000 ⁷⁸	Gelet, 2001 ⁷⁹	Thuroff, 2003 ⁸⁰	Chaussy, 2003 ⁸¹	Chaussy, 2003 ⁸¹	Blana, 2004 ⁸²	Uchida, 2005 ⁸³	Blana, 2006 ⁸⁴	Uchida/ Illig, 2006 ⁸⁵	Uchida/ Illig, 2006 ⁸⁵	Uchida/ Ohkusa, 2006 ⁸⁶	Poissonnier, 2007 ⁸⁷
Design	CS	CT	CT	CS	CS (HIFU + TURP)	CS	CT		CS (AS before HIFU)	CS	CS	CS
Followup, months	17.6	19	13.6	18.7	10.9	22.5	14	13	6	6	23.3	12-121
Number of patients	82	102	402	96	175	146	72	223	154	96	63	227
Mean age	71	70.8	69.3	65.8	68.4	66.9	72	68.2	67.9	69.2	70.5	68.8
% with T1-2	100	100	100	100	100	100	100	100	100	100	100	100
Mean PSA	8.11	8.38	10.9	8.6	8	7.6	8.1	11.3	10.5	8.9	11.2	6.99
% Gleason ≥7		46	9.3 (with 8-10)	30	25.7		8 (with 8-10)				6 (with 8-10)	33
Prostate volume, cm ³	34.9	33.3	28	21.7	20.5	23	22.1	23.5	22	25.7	28.5	23.9
HIFU device	Ablatherm	Ablatherm	Ablatherm	Ablatherm	Ablatherm	Ablatherm	Sonablate	Ablatherm	Sonablate	Sonablate	Sonablate	Ablatherm
HIFU treatments	1.92	1.7	1.4	1.25	1.04	1.17	1.2					1.4
PSA nadir			0.6	0.48	0.48	0.07					1.38	0.33
Progression free survival,* %	68-83	66		84.2	80	87	76				75	66
												Initial PSA PSA <4 - 90% 4.1-10-57% 10.1-15-61% nadir PSA <0.5 - 89% 0.51 -1 - 76% PSA >1.1 68%
Biopsy, % negative	78	75	87.2	87.7	81.6	93.4	68	22 needed second HIFU	69	66	87	
Adverse events												
Mild to moderate incontinence	15.8	18.6	13.1	15.4	6.9	10.2	1.4	7.6			2	12
Severe incontinence	4.8	4	1.5	0	0	0	0	0			0	1
Impotence	23	24.5	8.7	40	31.8	52.7	39	49.8			23.5	No erection-31%
Rectourethral	1.2	0.98	1.2			0.7	1.4	0			2	

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Table C20. Patient outcomes after high-intensity focused ultrasound therapy for localized prostate cancer (continued)

Author, Year	Gelet, 2000 ⁷⁸	Gelet, 2001 ⁷⁹	Thuroff, 2003 ⁸⁰	Chaussy, 2003 ⁸¹	Chaussy, 2003 ⁸¹	Blana, 2004 ⁸²	Uchida, 2005 ⁸³	Blana, 2006 ⁸⁴	Uchida/ Illig, 2006 ⁸⁵	Uchida/ Illig, 2006 ⁸⁵	Uchida/ Ohkusa, 2006 ⁸⁶	Poissonnier, 2007 ⁸⁷
fistula												
Urethral stenosis	20.7	16.7	3.6	27.1	8	11.7	18	19.7			24	12
Length of stay							5					
Quality of life (IPSS)				2.36	1.86	No change	No change	No change				>16-31% 7-15-38%

* progression free survival definitions:

CT - clinical trial, CS - case series, HIFU - High-intensity focused ultrasound, TURP - transurethral resection of the prostate, AS - androgen suppression therapy, IPSS - International prostate symptom score

Author, Year

Definition of biochemical failure

Gelet, 2000⁷⁸ 3 successive increases of PSA with PSA velocity >0.75ng/ml/year
 Gelet, 2001⁷⁹ 3 successive increases of PSA with PSA velocity >0.75ng/ml/year
 Chaussy, 2003⁸¹ Constant PSA level (ASTRO)
 Chaussy, 2003⁸¹ Constant PSA level (ASTRO)
 Blana, 2004⁸² Constant PSA <1ng/ml
 Uchida, 2005⁸³ 3 consecutive increases in PSA >1ng/ml
 Blana, 2006⁸⁴ increase of PSA >0.2 ng/ml after the last control
 Uchida, 2006⁸⁶ 3 consecutive increases in PSA >1.38ng/ml
 Poissonnier, 2007⁸⁷ Any positive biopsy or a PSA >1 ng/ml with three consecutive rises

Table C21. Proton radiation for localized prostate cancer

Author	Yonemoto, 1997 ⁸⁸ Phase I/II Clinical Trial	Slater, 1999 ⁸⁹ Case Series	Slater, 2004 ⁹⁰ Case Series	Rossi, 2004 ⁹¹ Case Series	Nihei, 2005 ⁹² Phase I/II Clinical Trial
Treatment	45 Gy photon-beam irradiation to the pelvis and 30 CGE to the prostate with 250-MeV protons, total dose 75 CGE in 40 fractions	Conformal radiation doses of 74 to 75 CGE with protons alone or combined with photons in 40 fractions	Conformal proton boost of 30 CGE with 225–250 MeV in 15 fractions to the prostate and seminal vesicles, followed by 45 Gy of photon radiation	Conformal proton radiation with 74–75 CGE followed by 45 Gy of 3D pelvic photon radiation	50 Gy/25 fractions photon irradiation to the prostate and the bilateral seminal vesicles followed by proton boost therapy of 26 GyE/13 fractions to the prostate alone. Phase II clinical trial
Follow up, months	20.2	43	63	62	30
No. of patients	106	319	1,255	1,000	30
% with T>2	18	0	4	0	23
% Gleason >7	12	6	7	7	10
Definitions of outcomes	Disease free survival; negative DRE and normalized PSA (<4.0 rig/ml). Local failure - increasing size of the tumor or nodule, or a continued abnormal prostate with rising PSA. Distant failure; any evidence of metastasis outside the primary site and regional lymph nodes.	Disease free survival; no symptoms Negative DRE and radionuclide scans. Biochemical disease-free survival; 3 consecutive PSA rises >10% or initiation of androgen therapy (American College of Radiology)	Biochemical disease-free survival; 3 consecutive rises in PSA, date of failure –midway between the nadir and first rise (ASTRO)	Biochemical disease-free survival; 3 consecutive rises in PSA, date of failure – midway between the nadir and first rise (ASTRO)	Biochemical disease-free survival; 3 consecutive rises in PSA, date of failure midway between the nadir and first rise (ASTRO)
Total survival	96	100	100	100	100
Disease-free survival, %	86	97			
Biochemical disease-free survival		88	73	In patients <60 years -75 In patients >60 years -74	77
Local survival, % negative biopsy	97.2				
Distant failure	7.5	2.5			
% complications					
Urinary, Grade 1	0				13.3
Urinary, Grade 2	3.8	5			20
Urinary, Grade 3	0	0	1		0
Urinary, Grade 4	0	0	0		0
GI, Grade 1	4.8				60
GI, Grade 2	3.8	6			20
GI, Grade 3	0	0	1		0
GI, Grade 4	0	0	0		0
Hematuria	3.8				
Rectal bleeding	8.7		0.2		

CGE = cobalt-gray equivalent

Table C22. PCOS: Reason for condition specific bother for responders reporting bother on urinary, bowel, and sexual questions* (Potosky, 2004)⁹³

Domain	RP† (n = 901)	EBR† (n = 286)	Odds Ratio (95% CI)
Urinary bother‡			
Too far from the bathroom	22.1 (24.0)	30.1 (24.9)	1.32 (0.83; 2.13)
Embarrassment about going too often	14.7 (15.2)	13.3 (11.9)	1.32 (0.83; 2.13)
Frequent urination	30.6 (31.6)	34.3 (31.3)	1.01 (0.68; 1.51)
Urination at night	41.6 (43.2)	51.9 (47.2)	0.84 (0.58; 1.22)
Urgency in urination	32.7 (34.2)	44.6 (39.9)	0.84 (0.58; 1.22)
Slow or difficult urination	32.7 (34.2)	44.6 (39.9)	0.78 (0.53; 1.12)
Bowel bother‡			
Diarrhea	11.2 (11.5)	16.6 (15.3)	0.70 (0.4; 1.22)
Tenderness during bowel movements	6.8 (7.3)	9.7 (8.4)	0.85 (0.46; 1.56)
Bleeding with bowel movements	7.5 (8.0)	14.7 (13.0)	0.58 (0.31; 1.06)
Passing mucus from rectum	5.1 (5.4)	14.4 (13.1)	0.36 (0.20; 0.66)
Sexual bother§			
Lack of sexual interest	42.7 (41.7)	40.6 (43.8)	0.92 (0.63; 1.32)
Lack of sexual enjoyment	53.1 (52.2)	45.5 (48.9)	1.14 (0.80; 1.64)
Inability to satisfy spouse or partner	57.5 (56.4)	46.1 (50.3)	1.28 (0.88; 1.86)
Orgasm difficult	47.8 (47.2)	43.4 (46.0)	1.05 (0.73; 1.51)
Orgasm satisfying	43.4 (42.4)	38.2 (41.4)	1.04 (0.72; 1.51)
Erectile difficulties	63.4 (62.0)	56.5 (61.2)	1.03 (0.71; 1.49)

* EBR is the referent group. Adjusted percentages are from separate logistic regression models, each adjusted for treatment propensity score, age, baseline function, race, comorbidity, and educational level.

† RP = radical prostatectomy, EBR = external beam radiation. Values in columns are unadjusted percentages, in parentheses, adjusted percentages.

‡ Percentages and OR for bother are somewhat/a lot versus not at all.

§ For bother items, percentages refer to patients reporting bother of a lot versus somewhat/not at all.

Table C23. Adjusted percentage distributions for satisfaction by characteristics at 24 months* (Hoffman, 2003)⁹⁴

Variable	Percent Satisfied (95% CI)	Wald Chi-Square Test p Value
Treatment		<0.01
No treatment	50.5 (42.5; 58.8)	
AD	66.3 (58.0; 74.6)	
Radiation	69.4 (64.6; 74.2)	
Free of PC		<0.01
No	49.1 (42.0; 56.3)	
Don't know	53.7 (48.7; 58.7)	
Yes	66.4 (63.2; 69.6)	
Bowel urgency		0.03
Almost every day	38.4 (22.0; 54.8)	
Some days	62.1 (56.6; 67.7)	
Rarely or not at all	60.5 (57.7; 63.3)	
Urinary leakage		<0.02
At least once a day	53.7 (48.6; 58.8)	
Once a week or less	59.7 (55.0; 64.4)	
Not at all	64.2 (60.8; 67.7)	
Erectile dysfunction		0.04
Cannot get any erections	58.1 (54.6; 61.5)	
Some or a lot of difficulty	61.7 (57.2; 66.1)	
No or little difficulty	65.9 (60.8; 71.1)	
General health (24 month followup)		<0.01
Excellent	71.3 (65.6; 77.0)	
Very good	65.2 (61.3; 69.2)	
Good	54.8 (50.5; 59.2)	
Fair	52.0 (45.3; 58.6)	
Cancer or treatment limits activities		<0.01
A lot or some	41.7 (33.2; 50.2)	
Only a little	52.9 (47.1; 58.8)	
Not at all	65.5 (62.4; 68.5)	
Cancer treatment affects relationships with spouse/friends		<0.01
A lot or some	43.9 (37.8; 50.0)	
A little	54.6 (49.5; 59.6)	
Not at all	68.1 (64.8; 71.3)	

* Weighted to reflect all eligible PC patients in the study area

Table C24. Association of bowel, urinary, and sexual function with patients' perception of the problem and satisfaction at 24 months post diagnosis*

Function at 24 Months	No Problem % Satisfied	Small/Very Small % Satisfied	Moderate/Big % Satisfied
Urgent bowel movements			
Rarely or not at all	64.3	57.7	35.2
Some days	65.5	55.1	29.7
Almost everyday	45.8	26.1	19.2
Leak or drip urine			
Not at all	69.9	59.9	--
Once a week or less	67.6	54.0	47.0
Daily or more often	73.3	48.8	31.6
Difficulty keeping an erection			
None or little	84.3	73.6	42.8
Some or a lot	77.3	74.4	52.1
No erections	62.8	63.5	48.2

*Weighted to reflect all eligible PC patients in the study area

Table C25. QOL studies of treatments for localized prostate cancer in nonRCTs

Study	Study Type/Patients/Interventions	Quality of Life Outcomes					
Lee, 2001 ⁹⁵	Prospective cohort study N = 98 T1/T2 patients enrolled Interstitial brachytherapy (IB): n = 44 [I-125, 144 Gy; 11 patients received androgen deprivation therapy before IB, to reduce size of prostate gland] Electron beam radiotherapy (EBRT): n = 23 [median dose = 70.2 Gy; 2 patients received androgen deprivation therapy before EBRT] Radical prostatectomy (RP): n = 23 [3 patients received androgen deprivation therapy before RP] <u>Age [median (range)]</u> IB = 67.1 (49 – 79) EBRT = 68.8 (51 – 79) RP = 61.0 (42 – 68) <u>Response rate</u> All patients = 91% (90 patients)	HRQOL scores					
		Measure/ Treatment	Mean (SD) - Baseline	Mean (SD) – 1 Month	Mean (SD) – 12 Months	p-Value Overall Within Treatment Group	p-Value B vs. 12 Months
		FACT-P					
		IB	138.4 (17.0)	120.5 (21.7)	138.5 (14.2)	0.0001<0.01	0.88
		EBRT	137.1 (12.1)	129.5 (21.0)	136.9 (15.6)		0.08
		RP	138.3 (14.7)	117.7 (18.3)	140.4 (14.9)		<0.01
		FACT-G					
		IB	100.7 (11.8)	92.5 (14.7)	102.2 (9.1)	<0.01	0.29
		EBRT	99.9 (7.9)	96.1 (12.5)	101.0 (10.1)	0.17	0.56
		RP	99.8 (9.6)	88.9 (13.2)	101.9 (11.3)	<0.01	0.28
		PWB					
		IB	25.9 (2.8)	21.6 (4.7)	25.3 (2.6)	<0.01	0.23
		EBRT	25.2 (2.2)	22.6 (4.7)	25.1 (4.1)	<0.01	0.91
		RP	26.3 (2.3)	20.9 (5.0)	26.3 (2.5)	<0.01	0.92
		FWB					
		IB	23.3 (4.4)	18.9 (6.4)	24.1 (3.7)	<0.01	0.18
		EBRT	22.9 (3.2)	21.7 (5.0)	23.2 (4.8)	0.25	0.65
		RP	23.6 (4.3)	16.5 (5.1)	23.3 (4.1)	<0.01	0.72
IPSS							
IB	8.3 (6.0)	20.8 (7.7)	10.4 (7.3)	<0.01	0.10		
EBRT	11.9 (6.4)	13.8 (7.5)	8.5 (5.4)	<0.01	0.01		
RP	12.5 (9.3)	17.2 (10.3)	5.5 (3.7)	<0.01	<0.01		
FACT-P = Functional Assessment of Cancer Therapy – Prostate; FACT-G = FACT – general; PWB = physical well-being; FWB = functional well-being; IPSS = International Prostate Symptom Score							
Schapira, 2001 ⁹⁶	Prospective observational study N = 122 T1/T2 patients Radical prostatectomy (RP): n = 42 [during the course of the study, 6 patients received hormonal therapy and 2 had radiation therapy] Radiation therapy (RT): n = 51 [during the course of the study, 12 patients received hormonal therapy] Expectant management (EM): n = 29 [during the course of the study, 7 patients received hormonal therapy and 4 had radiation therapy]	UCLA-PCI scores					
		Domain/treatment	Mean Score - Baseline	Mean Score – 3 Months	Mean Score – 12 Months		
		Urinary bother					
		RP	82	57	67		
		RT	80	77	81		
		EM	86	86	84		
		p-values (across treatment groups)					
			NS	NS	NS		
		Sexual bother					
		RP	64	28	29		
		RT	55	55	60		
		EM	56	67	62		
		p-values (across treatment groups)					
			NS	0.02*	NS		
		Bowel bother					
RP	91	90	86				
RT	86	76	77				

Table C25. QOL studies of treatments for localized prostate cancer in nonRCTs (continued)

Study	Study Type/Patients/Interventions	Quality of Life Outcomes					
	Age [median (range)]	EM	86	85	81		
	RP = 64 (58-68)	p-values (across treatment groups)	NS	0.05**	NS		
	RT = 73 (68-75)	* RP vs. RT and RP vs. EM					
	EM = 73 (70-78)	** RP vs. RT					
		Incontinence and impotence rates (based on UCLA-PCI responses)					
		Side-effect/treatment	Baseline – n (%)	3 months – n (%)	12 months – n (%)		
		Incontinence					
		RP	1 (2)	31 (76)	16 (44)		
		RT	2 (4)	4 (9)	3 (8)		
		EM	0 (0)	0 (0)	1 (4)		
		Impotence					
		RP	14 (35)	42 (100)	33 (89)		
		RT	30 (61)	33 (77)	30 (75)		
		EM	16 (55)	17 (63)	17 (68)		
		SF-36 scores					
		Domain/treatment	Mean score - baseline	Mean score – 3 months	Mean score - 12 months		
		General health perceptions					
		RP	74	71	71		
		RT	60	62	59		
		EM	64	67	68		
		p-values (across treatment groups)	NS	NS	NS		
Soderdahl, 2005 ⁹⁷	Prospective longitudinal comparative study	UCLA-PCI scores					
	N = 452 T1c/T2 patients recruited [334 responded to baseline questionnaire; 250 completed all surveys]	Domain	Mean score - baseline	Mean 1 month	Mean 6 months	Mean 12 months *	P-values
	Open radical prostatectomy (ORP): n = 86	Sexual bother					
		ORP	68	19	22	26	
		LRP	61	23	25	26	
		Brachy	57	37	45	44	P <0.001 [brachy were significantly less bothered by sexual problems than surgery]
	Laparoscopic radical prostatectomy (LRP): n = 93	Urine bother					
		ORP	87	31	65	74	
		LRP	83	24	65	69	
		Brachy	81	44	70	78	P <0.001 [RP more bother than brachy]
	Brachytherapy (Brachy): n = 71 [Pd-103, 115 Gy mean dose]	Bowel bother					
		ORP	89	76	90	87	
		LRP	85	68	85	87	
		Brachy	84	63	76	83	P = 0.07 [brachy had marginally lower scores (more bother) than surgery]
	Age [median]: ORP = 59 LRP = 61 Brachy = 68	Scale range = 0-100					

Table C25. QOL studies of treatments for localized prostate cancer in nonRCTs (continued)

Study	Study Type/Patients/Interventions	Quality of Life Outcomes																																																																	
		<p>SF-36 scores “After each treatment, there was an initial drop-off of general domain scores, which returned to baseline over time.” Profiles of changes were not different between groups for these scales Physical functioning (P = 0.26); Limitations secondary to emotional problems (P = 0.57) Vitality (P = 0.46); Mental health (P = 0.35); Bodily pain (P = 0.46); General health (P = 0.92); Health transition (P = 0.55).</p> <p>Scale change profile was marginally significantly different between groups for: Limitations attributable to physical problems (P = 0.052) Social functioning (P = 0.06) “At 12 months, there were no significant differences among groups.”</p>																																																																	
		<p>Potency (sexual function)</p> <table border="1"> <thead> <tr> <th>Treatment</th> <th>Mean Score - Baseline</th> <th>Mean Score - 1 Month</th> <th>Mean Score - 6 Months</th> <th>Mean Score - 12 Months</th> <th>P-Values</th> </tr> </thead> <tbody> <tr> <td colspan="6">ORP</td> </tr> <tr> <td>Bilateral NS</td> <td>65</td> <td>9</td> <td>20</td> <td>30</td> <td rowspan="3">No statistical difference by ORP</td> </tr> <tr> <td>Unilateral NS</td> <td>62</td> <td>8</td> <td>20</td> <td>29</td> </tr> <tr> <td>Non NS</td> <td>56</td> <td>15</td> <td>20</td> <td>26</td> </tr> <tr> <td colspan="6">LRP</td> </tr> <tr> <td>Bilateral NS</td> <td>75</td> <td>7</td> <td>12</td> <td>15</td> <td rowspan="3">P <0.001 [baseline sexual function was worse in non-NS LRP]</td> </tr> <tr> <td>Unilateral</td> <td>75</td> <td>7</td> <td>13</td> <td>20</td> </tr> <tr> <td>Non NS</td> <td>53</td> <td>6</td> <td>12</td> <td>19</td> </tr> </tbody> </table>	Treatment	Mean Score - Baseline	Mean Score - 1 Month	Mean Score - 6 Months	Mean Score - 12 Months	P-Values	ORP						Bilateral NS	65	9	20	30	No statistical difference by ORP	Unilateral NS	62	8	20	29	Non NS	56	15	20	26	LRP						Bilateral NS	75	7	12	15	P <0.001 [baseline sexual function was worse in non-NS LRP]	Unilateral	75	7	13	20	Non NS	53	6	12	19															
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Fulmer, 2001 ⁹⁸	<p>Prospective cohort study N = 127 T1/T2 patients Hormonobrachytherapy with external beam radiotherapy (HBTC): n = 40 [high-risk patients] [received 40-45 Gy of EBRT followed by brachytherapy + antiandrogen + LHRH agonist] Hormonobrachytherapy (HBT): n = 45 [low-risk patients] [received brachytherapy + antiandrogen + flutamide] Radical retropubic prostatectomy (RP): n = 42</p>	<p>Voiding and sexual function scores</p> <table border="1"> <thead> <tr> <th>Domain/Treatment</th> <th>Baseline - Mean Score (SE)</th> <th>3 Months - Fold Change (95% CI)*</th> <th>6 Months - Fold Change (95% CI)*</th> <th>12 Months - Fold Change (95% CI)*</th> </tr> </thead> <tbody> <tr> <td colspan="5">AUASS</td> </tr> <tr> <td>RP</td> <td>7.17 (0.98)</td> <td>-</td> <td>-</td> <td>-</td> </tr> <tr> <td>HBTC</td> <td>7.57 (1.06)</td> <td>1.66 (1.15; 2.40)</td> <td>1.55 (1.11; 2.17)</td> <td>1.36 (0.93; 1.98)</td> </tr> <tr> <td>HBT</td> <td>6.69 (0.93)</td> <td>1.40 (0.99; 1.98)</td> <td>1.38 (1.01; 1.87)</td> <td>1.32 (0.94; 1.88)</td> </tr> <tr> <td colspan="5">IAUA</td> </tr> <tr> <td>RP</td> <td>3.87 (0.42)</td> <td>-</td> <td>-</td> <td>-</td> </tr> <tr> <td>HBTC</td> <td>4.63 (0.61)</td> <td>1.26 (0.95; 1.66)</td> <td>1.26 (0.97; 1.63)</td> <td>1.27 (0.95; 1.68)</td> </tr> <tr> <td>HBT</td> <td>4.10 (0.48)</td> <td>1.02 (0.78; 1.32)</td> <td>1.04 (0.82; 1.33)</td> <td>1.10 (0.84; 1.43)</td> </tr> <tr> <td colspan="5">OAUUA</td> </tr> <tr> <td>RP</td> <td>3.32 (0.62)</td> <td>-</td> <td>-</td> <td>-</td> </tr> <tr> <td>HBTC</td> <td>3.25 (0.70)</td> <td>2.48 (1.63; 3.77)</td> <td>2.18 (1.50; 3.16)</td> <td>1.68 (1.10; 2.57)</td> </tr> <tr> <td>HBT</td> <td>2.64 (0.55)</td> <td>2.28 (1.55; 3.38)</td> <td>2.17 (1.53; 3.06)</td> <td>1.95 (1.31; 2.89)</td> </tr> </tbody> </table>	Domain/Treatment	Baseline - Mean Score (SE)	3 Months - Fold Change (95% CI)*	6 Months - Fold Change (95% CI)*	12 Months - Fold Change (95% CI)*	AUASS					RP	7.17 (0.98)	-	-	-	HBTC	7.57 (1.06)	1.66 (1.15; 2.40)	1.55 (1.11; 2.17)	1.36 (0.93; 1.98)	HBT	6.69 (0.93)	1.40 (0.99; 1.98)	1.38 (1.01; 1.87)	1.32 (0.94; 1.88)	IAUA					RP	3.87 (0.42)	-	-	-	HBTC	4.63 (0.61)	1.26 (0.95; 1.66)	1.26 (0.97; 1.63)	1.27 (0.95; 1.68)	HBT	4.10 (0.48)	1.02 (0.78; 1.32)	1.04 (0.82; 1.33)	1.10 (0.84; 1.43)	OAUUA					RP	3.32 (0.62)	-	-	-	HBTC	3.25 (0.70)	2.48 (1.63; 3.77)	2.18 (1.50; 3.16)	1.68 (1.10; 2.57)	HBT	2.64 (0.55)	2.28 (1.55; 3.38)	2.17 (1.53; 3.06)	1.95 (1.31; 2.89)
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Table C25. QOL studies of treatments for localized prostate cancer in nonRCTs (continued)

Study	Study Type/Patients/Interventions	Quality of Life Outcomes			
	<u>Age [median]</u>	VB			
	HBTC = 68	RP	3.58 (0.55)	-	-
	HBT = 66	HBTC	4.03 (0.58)	0.76 (0.47; 1.22)	0.85 (0.56 – 1.30)
	RP = 59	HBT	3.30 (0.48)	0.71 (0.46; 1.09)	0.78 (0.53 – 1.16)
	<u>Median followup (time since surgery)</u>	SF			
	8.2 months (range 0.2 – 37.0 months)	RP	4.24 (0.73)	-	-
		HBTC (n = 36)	9.75 (1.21)	-	0.70 (0.52; 0.93)
		HBT (n = 43)	7.69 (0.96)	-	0.54 (0.42; 0.69)
		SFB			
		RP	3.42 (0.60)	-	-
		HBTC (n = 36)	6.36 (0.76)	-	0.76 (0.58; 0.99)
		HBT (n = 43)	4.90 (0.70)	-	0.59 (0.47; 0.75)
		AUASS = AUA symptom score; IAUA = AUA Irritative subscale; OAU = AUA Obstructive subscale; VB = Voiding Bother; SF = Sexual function; SFB = Sexual Function Bother score			
		*Relative change or fold change of given BT group compared to RP (BT/RP). Numbers lower than one indicate lower scores in BT than in RP.			
Galbraith, 2001 ⁹⁹	Longitudinal survey study	Health-related quality of life score			
	N = 185 localized prostate cancer patients	Treatment	Baseline	6 Months	18 Months
	Watchful waiting (WW): n = 30	Watchful waiting	60.4	58.1	59.0
	Surgery (S): n = 59	Surgery	60.3	56.6	57.0
	Conventional radiation (CR): n = 25	Conventional radiation	59.6	59.5	57.2
	Proton beam therapy (PB): n = 24	Mixed-beam radiation	61.7	59.5	60.5
	Mixed-beam radiation (MB): n = 47	Proton-beam radiation	60.7	59.0	60.7
		p value			
		Higher score = higher QOL (range = 0-100)			
		Physical functioning			
		Treatment	Baseline	6 Months	18 Months
	<u>Age [mean]</u>	Watchful waiting	74	65	75
	WW = 73	Surgery	80	78	81
	S = 65	Conventional radiation	79	71	70
	CR = 71	Mixed-beam radiation	83	80	78
	PB = 68	Proton-beam radiation	84	84	78
	MB = 69	p value		<0.05 (PB vs. WW)	
		Higher score = higher functioning (range = 0-100)			
		General health			
		Treatment	Baseline	6 Months	18 Months
		Watchful waiting	48	50	54
		Surgery	57	61	58
		Conventional radiation	58	59	56
		Mixed-beam radiation	60	58	59
		Proton-beam radiation	53	58	60
		p value	<0.001 (MB vs. WW)		<0.01 (S vs. WW)
		Higher score = better health (range = 0-100)			

Table C26. QOL studies of treatments for localized prostate cancer in RCTs

Study	Study Type/Patients/Interventions	Quality of Life Outcomes			
Fransson, 2001 ¹⁰⁰	Randomized controlled trial N = 166 T1/T2 patients enrolled [30 patients died by date of questionnaire submission; 11 patients were excluded due to followup <6 months or progressed disease with progressive treatment before questionnaire]	EORTC QLQ-C30 (+3) Questionnaire			
	Radiation therapy (EBRT): n = 59 Deferred therapy (DT): n = 49	Domain	EBRT Mean Scores	DT Mean Scores	p Value
	<u>Age [mean (range)]</u> RT = 71.3 (49.1 – 83.0) DT = 72.8 (58.9 – 81.9)	Global health/QOL	68	70	
	<u>Median followup (from randomization date to time of questionnaire)</u> RT = 40.6 months DT = 30.4 months [p = 0.055]	Scores were linearly transformed to a 0 to 100 scale according to EORTC recommendations Increasing score = higher level of functioning			
	<u>Response rate</u> RT = 90% DT = 85%	QUFW94 Questionnaire			
		Variable	RT Mean Score (95% CI)	DT Mean Score (95% CI)	p Value
		General function			
		Limitation to daily activity caused by prostate carcinoma	1.8 (1.29; 2.39)	0.7 (0.19; 1.26)	0.001
		Urinary symptoms			
		Incontinence	1.5 (0.55; 2.18)	0.6 (0.13; 1.00)	0.008
	Limitation in daily activity caused by urinary problems	1.1 (0.63; 1.62)	0.9 (0.27; 1.47)	0.06	
	Urinary problems in general	1.8 (1.15; 2.42)	1.2 (0.60; 1.86)	0.227	
	Intestinal symptoms				
	Limitation in daily activity caused by intestinal problems	1.3 (0.73; 1.85)	0.3 (0.04; 0.48)	0.001	
	Planning of daily activity caused by intestinal problems	1.9 (1.19; 2.54)	1.0 (0.22; 1.72)	0.004	
	QUFW94 scores range from 0 (no problem/very good function) to 10 (many problems/very bad function)				

Table C26. QOL studies of treatments for localized prostate cancer in RCTs (continued)

Study	Study Type/Patients/Interventions	Quality of Life Outcomes			
Steineck, 2002 ¹⁰¹	Randomized controlled trial: SPCG-4 N = 376 T0/T1/T2 patients enrolled Age [mean (range)]: RP = 64.1 (48.0 - 74.0) WW = 64.8 (51.0 - 74.0) Median followup (from randomization date to time of questionnaire) RP = 50.0 months WW = 48.0 months	Sexual Dysfunction			
		Function - Outcome	RP [n / N Responding (%)]	WW [n / N Responding (%)]	Unadjusted Relative Risk (95% CI)
		Desire			
		Importance of sexual function – no or little importance	79 / 159 (50)	64 / 154 (42)	1.2 (0.9; 1.5)
		Penile stiffness			
		Erectile function - seldom or never sufficient for intercourse	129 / 161 (80)	71 / 158 (45)	1.8 (1.5; 2.2)
		Distress from erectile dysfunction – moderate or great distress	90 / 155 (58)	65 / 152 (43)	1.4 (1.0; 1.7)
		Distress from erectile dysfunction – great distress	46 / 155 (30)	26 / 152 (17)	1.7 (1.1; 2.7)
		Intercourse			
		Distress from decreased frequency – moderate or great distress	94 / 160 (59)	66 / 153 (43)	1.4 (1.1; 1.7)
		Orgasm			
		Distress from decreased frequency – moderate or great distress	88 / 158 (56)	65 / 152 (43)	1.3 (1.0; 1.6)
		Distress from compromised sexuality			
		Distress (if sexual function has declined) – moderate or great distress	87 / 156 (56)	62 / 154 (40)	1.4 (1.1; 1.8)
		For each question, some men did not respond. A number above unity indicates better function in the watchful waiting group.			
Urinary Tract Dysfunction					
Function - outcome	RP [n / N Responding (%)]	WW [n / N Responding (%)]	Unadjusted Relative Risk (95% CI)		
Global features					
Distress from obstructed voiding – moderate or great distress	34 / 164 (21)	34 / 157 (22)	1.0 (0.6; 1.5)		

Table C26. QOL studies of treatments for localized prostate cancer in RCTs (continued)

Study	Study Type/Patients/Interventions	Quality of Life Outcomes		
		Urinary leakage		
	Subjective estimation of the degree of leakage – moderate or severe leakage	30 / 163 (18)	3 / 152 (2)	9.3 (2.9; 29.9)
	Distress from urinary leakage – moderate or great distress	47 / 164 (29)	15 / 158 (9)	3.0 (1.8; 5.2)
	Regular dependence on some form of protective aid - yes	71 / 165 (43)	16 / 154 (10)	4.1 (2.5; 6.8)
	Regular dependence on diaper or urine bag - yes	23 / 165 (14)	1 / 154 (1)	21.5 (2.9; 157.0)
	Overall distress from all urinary symptoms – moderate or great distress	44 / 163 (27)	28 / 157 (18)	1.5 (1.0; 2.3)
	For each question, some men did not respond. A number above unity indicates better function in the watchful waiting group.			
		Psychological Symptoms		
	Function - outcome	RP [n / N Responding (%)]	WW [n / N Responding (%)]	Unadjusted Relative Risk (95% CI)
	Physical function			
	Decreased general physical capacity – the lowest five of seven possible categories	89 / 164 (54)	89 / 157 (57)	1.0 (0.8; 1.2)
	Low or moderate physical well-being – the lowest five of seven possible categories	68 / 164 (41)	78 / 157 (50)	0.8 (0.7; 1.1)
	Psychological function			
	Worry (moderate or high) - the highest five of seven possible categories	64 / 164 (39)	71 / 157 (45)	0.9 (0.7; 1.1)
	Low or moderate psychological well-being – the lowest five of seven possible categories	57 / 164 (35)	57 / 158 (36)	1.0 (0.7; 1.3)

Table C26. QOL studies of treatments for localized prostate cancer in RCTs (continued)

Study	Study Type/Patients/Interventions	Quality of Life Outcomes		
	Low or moderate subjective quality of life – the lowest five of seven possible categories	64 / 159 (40)	68 / 151 (45)	0.9 (0.7; 1.2)
	For each question, some men did not respond. CI denotes confidence interval.			
	Bowel Function			
	Function - Outcome	RP [n / N Responding (%)]	WW [n / N Responding (%)]	Unadjusted Relative Risk (95% CI)
	Fecal leakage – once a week or more	1 / 164 (1)	9 / 157 (6)	-
	Distress from fecal leakage – moderate to great	3 / 164 (2)	7 / 155 (5)	-
	Distress from all bowel symptoms	5 / 159 (3)	10 / 156 (6)	-

Figure C6. Search strategy

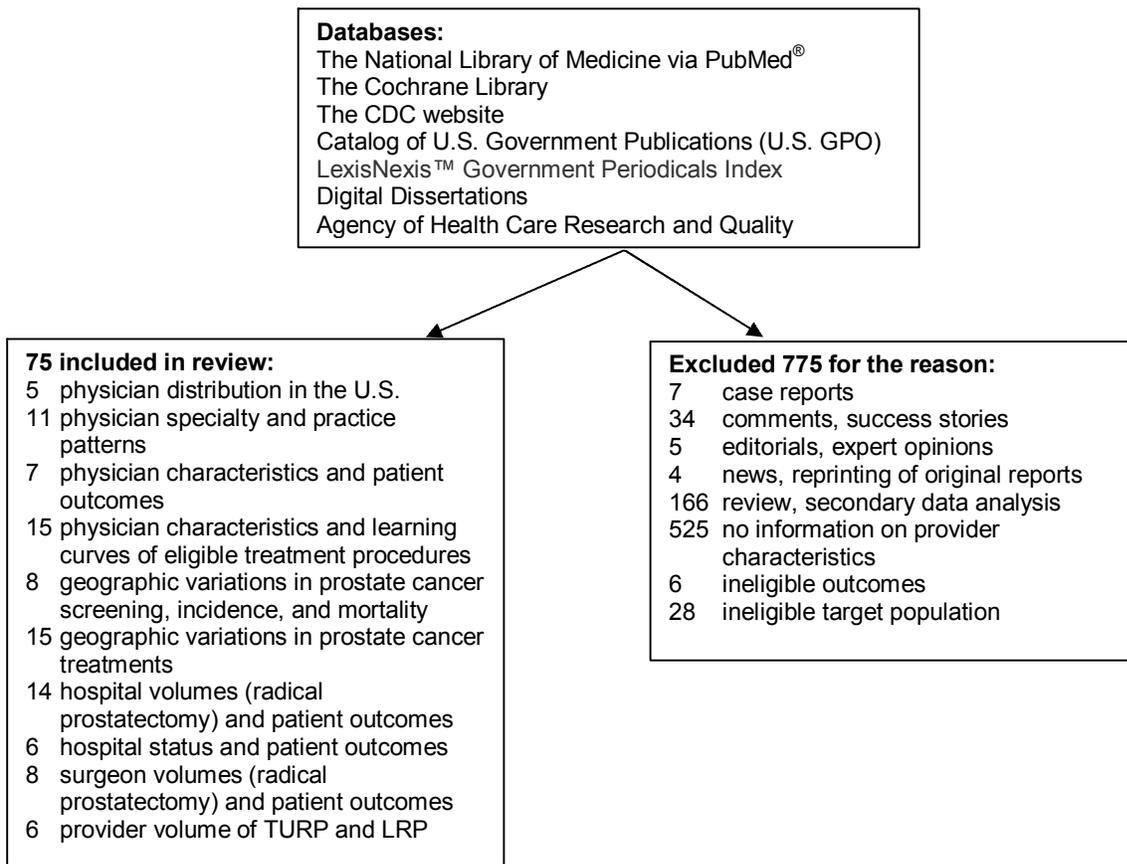


Table C27. Quality (% of maximum possible) of studies that assessed the association between patient outcomes and provider volumes

Outcomes (Means ± Standard Deviation)	All Studies	Mortality	Morbidity	Urinary Complications	Incontinence	Length of Stay	Cost	Readmission	Positive Margins
Criteria to score quality of the studies									
Quality, % of maximal	65.2±10.8	68.3±5.9	73.3±11.4	75.0±14.6	64.9±0.2	66.7±16.7	54±11.8	69.3	69.5±0.7
Study question clearly focused and appropriate	4.0±0.7	4.3±0.5	4.2±0.5	4.4±0.6	4.0±0.01	4.0±0.9	3.4±0.8	4	4
The objectives and primary hypothesis of the study clearly stated	2.1±1.4	1.9±1.1	2.1±1.8	2.8±2.0	1±0.01	2.6±1.7	2.1±1.0	1	3.9±0.3
Description of the target population	3.7±0.5	4.0±0.0	3.7±0.5	3.9±0.2	4±0.01	3.4±0.6	3.2±0.4	4	4
Description and clear definition of the exposure	4.3±0.7	4.3±0.9	4.7±0.5	4.9±0.5	5±0.01	4.6±0.7	3.4±0.8	5	3.9±0.3
Description and clear definition of primary outcomes	4.4±0.7	4.4±0.5	4.5±0.5	4.9±0.3	4.9±0.3	4.2±0.9	4.5±0.5	4	5±0.0
Description and clear definition of secondary outcomes	3.8±1.6	4.4±0.9	3.7±0.9	4.0±1.0	3.1±0.3	4.0±0.9	3.7±0.8	4	0.3±1.3
Validation of the measurements of the exposure	4.2±0.8	3.8±0.7	4.4±0.7	4.4±0.8	4.1±0.3	4.2±0.8	2.9±0.7	5	3.9±0.5
Validation of the measurements of the outcomes	4.5±0.5	4.1±0.3	4.3±0.4	4.4±0.5	4±0.01	4.7±0.5	4±0.0	4	4.1±0.3
The process of the subjects selection	3.4±0.6	3.3±0.5	3.4±0.6	3.4±0.6	3±0.01	3.3±0.6	2.9±0.7	4	3±0.0
The adequacy of the sampling (random selection or not) and selection bias	2.9±0.8	2.3±0.5	2.6±0.9	2.9±1.0	2±0.01	2.8±0.8	3±0.0	2	2.9±0.3
Was the sample size justified	2.0±0.1	2.0±0.0	2.0±0.2	1.9±0.2	2±0.01	2.0±0.2	1.7±0.5	2	2.0±0.0
Assessment of possible confounding factors	3.2±0.9	3.6±0.5	3.9±0.5	3.8±0.7	4±0.01	2.9±1.3	1.1±1.6	4	4.0±0.0
Validity of the measurements of confounding factors	4.0±1.3	4.2±0.4	4.4±0.8	4.3±1.0	4±0.01	3.8±1.9	1.3±2.0	4	5.0±0.0
Adjustment for confounding factors	2.8±2.4	4.8±0.4	4.9±0.7	4.8±0.9	5±0.01	2.5±2.4	1.1±1.6	5	5.0±0.0
Reporting of the statistical analysis	4.1±1.0	5±0.0	4.7±0.5	4.9±0.5	5±0.01	3.9±1.1	2.9±1.2	5	4.9±0.5
Precision of the reported estimates of the association	3.7±1.5	2.4±1.9	2.4±1.3	2.2±2.0	0.4±1.3	3.5±0.7	3.7±0.8	2	5±0.0
Use of multivariate models to assess crude and adjusted estimation	2.6±2.2	4.0±0.4	4.4±0.8	4.2±0.9	3.8±0.7	2.3±2.2	1.3±1.6	4	5±0.0

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Table C27. Quality (% of maximum possible) of studies that assessed the association between patient outcomes and provider volumes (continued)

Outcomes (Means ± Standard Deviation)	All Studies	Mortality	Morbidity	Urinary Complications	Incontinence	Length of Stay	Cost	Readmission	Positive Margins
Justification for statistical methods used to test hypothesis	3.2±2.1	4.8±0.4	4.9±0.7	4.8±0.9	5±0.01	3.1±1.9	1.1±1.6	5	5±0.0
Justification for subgroup analysis	1.9±1.9	1.9±1.7	2.7±2.5	2.2±2.6		2.8±1.8	2.2±1.4		0.3±1.3
Assessment of the limitations of the study	3.6±0.8	3.3±1.0	4.2±0.6	4.3±0.8	4±0.01	3.7±1.0	2.9±0.7	4	4±0.0
Results presentation	3.9±0.8	3.8±0.7	4.0±0.9	4.3±0.8	3.8±0.7	3.8±0.9	3.2±0.4	5	4.9±0.3
Justification for the results of the study	4.4±0.5	4.5±0.5	4.7±0.5	4.9±0.3	4.9±0.3	4.4±0.5	4±0.0	5	4.9±0.3
The appropriate conclusions of the study	3.4±0.8	3.4±1.0	4.2±0.5	4.4±0.6	4±0.01	3.9±0.8	3.7±0.5	4	2.9±0.3
Justification for conclusions in relation to tested hypotheses	3.7±0.9	3.8±1.3	4.6±0.6	4.8±0.5	4.9±0.3	4.0±0.9	3.7±0.5	5	2.9±0.3
Applicability of the studies findings	3.5±0.7	3.0±0.9	3.7±0.5	3.4±0.5	3±0.01	3.5±0.5	3.2±0.4	4	4±0.0

Table C28. Quality of the studies (% of maximum possible) by sponsorship, journal of publication, data sources, and country of publication (means ± standard deviations)

	Studies	Selection of Patients	Adjustment for Confounding Factors	Quality	Applicability
Sponsorship					
Grant	7	3.0 ± 0.6	3.6 ± 2.1	64.0 ± 11.9	3.3 ± 0.8
Unknown	8	3.3 ± 0.7	3.1 ± 2.4	65.0 ± 10.5	3.6 ± 0.5
Industry	2	3.5 ± 0.7	5.0±0.0	76.4 ± 19.2	3.0 ± 1.4
Journal of Publication					
General medicine	2	3.0 ± 0.01	5.0 ± 0.01	68.2 ± 4.5	2.5 ± 0.7*
Oncology	2	4.0 ± 0.01*	5.0 ± 0.01	79.6 ± 14.6	4.0 ± 0.01
Other	2	3.5 ± 0.7	2.5 ± 3.5	65.4 ± 9.6	4.0 ± 0.01*
Urology	7	2.9 ± 0.7*	3.0 ± 2.2	59.5±11.8	3.1 ± 0.7
Data used					
Administrative	10	3.2 ± 0.6	4.0 ± 1.9	67.4 ± 12.5	3.2 ± 0.8
Medical Records	7	3.1 ± 0.7	2.9 ± 2.4	63.9 ± 11.5	3.7 ± 0.5
Country where Study was Conducted					
Austria	1	3.0	0.0	54.3	3.0
Canada	1	3.0	5.0	62.9	2.0*
USA	15	3.2	3.7	66.9	3.5*

* significant differences at 95% confidence interval

Table C29. Geographic variations in prostate cancer screening, incidence, and mortality

Reference Period Design	Population Data Source	Exposure Definitions	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate
Lu-Yao, 1994 ¹⁰²	White men 50-70 years old from 9 areas in SEER program (~10% of the USA population)	Time trends and geographical variations in the detection and treatment of prostate cancer	Age-standardized Incidence; annual % change (EAPC) in rates by calendar year	Regression analysis. Pearson correlation between the average rates of incidence and mortality for each SEER area	Area	<i>Incidence/100,000</i>
1983-1989					Atlanta	279.4
					Connecticut	235.0
Retrospective cohort; ecologic analysis.	The National Center of Health Statistics				Detroit	284.6
					Hawaii	281.3
					Iowa	251.0
					New Mexico	284.6
Evidence II2B					San Francisco	249.3
Quality: 0.7				<i>Unit: Patient</i>	Seattle	348.9
					Utah	326.7
				<i>Risk adjustment:</i>		1989
				Age	Atlanta	384.5
					Connecticut	267.9
					Detroit	361.7
					Hawaii	502.3
					Iowa	332.3
					New Mexico	351.9
					San Francisco	368.2
					Seattle	606.8
					Utah	374.1
						Annual % change in rate
					Atlanta	7.7 (4.1-11.3)
					Connecticut	2.7 (0.6-4.8)
					Detroit	5.2 (3.2-7.3)
					Hawaii	10.0 (4.3-15.9)
					Iowa	5.0 (3.6-8.3)
					New Mexico	3.0 (0.8-5.3)
					San Francisco	6.6 (5.0-8.3)
					Seattle	12.0 (8.8-15.2)
					Utah	3.0 (0.3-5.7)
Kafadar, 1997 ¹⁰³	The U.S. Census population from 1953-1987	Time trends and geographic location by U.S. counties. The proportion of African-Americans	Age-standardized mortality among whites and nonwhites	Bivariate smoothing using calculation of age-specific rates; United States	Area	<i>Mortality/100,000</i>
1953-1987					Midwest	18.9-23.57
					Northeast	18.93-24.17
Ecologic analysis	The state Cancer Control Maps; The National Center of Health Statistics				South	17.16-22.02
					West	18.45-23
Evidence II2B				<i>Risk adjustment:</i>		1953-1972, Not Whites
				age, proportion of	Midwest	16.34-39.12

Table C29. Geographic variations in prostate cancer screening, incidence, and mortality (continued)

Reference Period Design	Population Data Source	Exposure Definitions	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate			
Quality: 0.9				African Americans	Northeast South West Midwest Northeast South West Midwest Northeast South West	0-45.98 28.29-44.33 6.31-30.69 <i>1973-1987, Whites</i> 20.01-24.01 20.5-25.59 18.73-23.32 20.06-26.86 <i>1973-1987, Not Whites</i> 12.18-45.97 9.14-42.47 29.92-51 17.96-32.8			
Jemal, 2002 ¹⁰⁴ 1970-1989 Ecologic analysis Evidence II2B Quality: 0.85	Population estimates in the U.S. for the years 1970-1989 by 5-year age groups U.S. Bureau of Census; The National Center for Health Statistics	Geographic locations, race	indirectly age-adjusted mortality	Spatial scan statistic; Poisson distribution <i>Unit: Counties</i> <i>Risk adjustment: education and agricultural employment</i>	<i>Areas White males</i> (United States) Northwest quadrant New England Maryland, Virginia, Pennsylvania Michigan, Ohio, Indiana, Illinois South Carolina, North Carolina Montana, North Dakota, Wyoming Minnesota, Iowa, Wisconsin California, Oregon Washington, Oregon Utah, Nevada, Colorado, Arizona Iowa, Missouri Vermont, New	<i>Age adjusted mortality/100,000 person years</i> <i>Rate</i> 20.2 21.5 21.3 21.7 20.8 22 23.2 22.8 21.9 21.6 22.4 25.3 22.8	<i>Rate ratio</i> 1 1.064 1.055 1.074 1.028 1.09 1.147 1.126 1.084 1.068 1.107 1.249 1.126	<i>P value</i> - 0.0001 0.0001 0.0001 0.0001 0.0027 0.0001 0.0001 0.0001 0.0005 0.017 0.0235 0.0001	

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Table C29. Geographic variations in prostate cancer screening, incidence, and mortality (continued)

Reference Period Design	Population Data Source	Exposure Definitions	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate
					Hampshire, Maine	
					Massachusetts, Rhode Island	23 1.139 0.0001
					Massachusetts, Connecticut	21.6 1.07 0.0194
					Maryland, Delaware	22.6 1.116 0.0001
					Kentucky, Ohio, Indiana	23 1.135 0.0001
					Wisconsin	21.5 0.0033
					<i>Black Males</i>	
					(United States)	28.6 1 -
					South Atlantic	31.9 1.114 0.0001
					Alabama	33.3 1.161 0.005
					Ohio, Indiana, Michigan, Kentucky	30.8 1.077 0.0561
					North Carolina, South Carolina	33.7 1.177 0.0001
					Florida, Georgia	33.7 1.177 0.0001
					Maryland, Virginia, Delaware	33.2 1.16 0.0001
					Georgia, North Carolina	32.7 1.142 0.0001
					Georgia	37.8 1.319 0.02
Jemal, 2005 ¹⁰⁵	40% of the U.S. male population ages 40 years for 1995 to 2000	Geographic locations; race, degree of urbanization as a proxy for access to medical care	Average age adjusted to the year 2000 U.S. population standard incidence and mortality rates/100,000 men	Poisson distribution <i>Unit: States</i>	<i>Location</i> <i>White men</i>	<i>Age adjusted mortality/100,000</i>
1995-2000					Alaska	258.2
Retrospective cohort, ecologic analysis	The National Center for Health Statistics and the North American Association of Central Cancer Registries (SEER)			<i>Risk adjustment: age and race</i>	Arizona	215.9
Evidence II2B					Colorado	274.4
Quality: 0.85					Connecticut	332.4
					District of Columbia	320.5
					Atlanta	311.4
					Hawaii	315.3
					Idaho	283.9
					Illinois	278.7
					Iowa	297.1

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Table C29. Geographic variations in prostate cancer screening, incidence, and mortality (continued)

Reference Period Design	Population Data Source	Exposure Definitions	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate
					Kentucky	220.0
					Louisiana	302.0
					Maine	296.2
					Massachusetts	353.8
					Michigan	320.1
					Montana	278.1
					Nebraska	308.7
					New Hampshire	287.3
					New Jersey	330.1
					North Carolina	271.2
					North Dakota	357.4
					Oregon	298.9
					Pennsylvania	296.6
					Rhode Island	266.8
					South Carolina	286.9
					Utah	385.8
					Washington	298.8
					West Virginia	250.7
					Wisconsin	318.2
					Wyoming	279.0
					<i>Black men</i>	
					Arizona	154.8
					Colorado	172.6
					Connecticut	167.6
					District of Columbia	164.2
					Atlanta	169.9
					Illinois	167.4
					Iowa	180.3
					Kentucky	155.2
					Louisiana	164.4
					Massachusetts	142.9
					Michigan	153.7
					Nebraska	142.5
					New Jersey	167.2
					North Carolina	196.7
					Oregon	177.3
					Pennsylvania	172.7
					Rhode Island	129.2
					South Carolina	195.9

Table C29. Geographic variations in prostate cancer screening, incidence, and mortality (continued)

Reference Period Design	Population Data Source	Exposure Definitions	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate
					Washington	146.6
					West Virginia	170.1
					Wisconsin	145.1
					<i>White men</i>	<i>Incidence of localized PC</i>
					Alaska	258.2
					Arizona	215.9
					Colorado	274.4
					Connecticut	332.4
					District of Columbia	320.5
					Atlanta	311.4
					Hawaii	315.3
					Idaho	283.9
					Illinois	278.7
					Iowa	297.1
					Kentucky	220.0
					Louisiana	302.0
					Maine	296.2
					Massachusetts	353.8
					Michigan	320.1
					Montana	278.1
					Nebraska	308.7
					New Hampshire	287.3
					New Jersey	330.1
					North Carolina	271.2
					North Dakota	357.4
					Oregon	298.9
					Pennsylvania	296.6
					Rhode Island	266.8
					South Carolina	286.9
					Utah	385.8
					Washington	298.8
					West Virginia	250.7
					Wisconsin	318.2
					Wyoming	279.0
					<i>Black men</i>	
					Alaska	457.7
					Arizona	255.9
					Colorado	363.4

Table C29. Geographic variations in prostate cancer screening, incidence, and mortality (continued)

Reference Period Design	Population Data Source	Exposure Definitions	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate	
					Connecticut	500.5	
					District of Columbia	516.2	
					Atlanta	481.5	
					Hawaii	351.8	
					Illinois	386.5	
					Iowa	485.2	
					Kentucky	317.4	
					Louisiana	381.8	
					Massachusetts	487.6	
					Michigan	561.9	
					Nebraska	389.7	
					New Jersey	494.8	
					North Carolina	380.7	
					Oregon	384.6	
					Pennsylvania	483.1	
					Rhode Island	309.3	
					South Carolina	454.6	
					Utah	475.8	
					Washington	421.2	
					West Virginia	400.8	
					Wisconsin	511.6	
Escobedo, 2004 ¹⁰⁶	3,274 African American men in Connecticut, Iowa, and New Mexico diagnosed with localized or regional prostate cancer in 1979-1998	Time trends in periods before (1979-1986), during (1987-1990) and after introduction of the PSA test (1991-1998); geographic locations	Age-adjusted to the 1970 U.S. standard incidence and mortality	Poisson distribution. <i>Unit:</i> patients	<i>Time and regions</i> <i>Connecticut 1973-1988</i> <54 55-64 65-74 >75 <i>1989-1998</i> <54 55-64 65-74 >75 <i>1973-1988</i> <i>By stage</i> Local/regional Distant Unstaged <i>1989-1998</i> Local/regional	<i>Incidence Rate</i> 3.8 210.3 721.5 1157.3 13.7 567.2 1450 1495.2 63 36 10.9 158.1	<i>Rate Ratio</i> 2.7 2.01 1.29 2.51
1979-1998							
Retrospective cohort							
Evidence II2B	The National Center for Health Statistics (NCHS), SEER database						
Quality: 0.75							

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Table C29. Geographic variations in prostate cancer screening, incidence, and mortality (continued)

Reference Period Design	Population Data Source	Exposure Definitions	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate	
					Distant	26.1	0.73
					Unstaged	23.5	2.16
					Overall		
					Before PSA	109.9	
					During PSA	207.8	1.89
					<i>Iowa</i>		
					1973–1988		
					<54	4	
					55–64	211.7	
					65–74	654.2	
					>75	1275.1	
					1989–1998		
					<54	13	3.25
					55–64	512.1	2.42
					65–74	1253.6	1.92
					>75	1589.9	1.25
					1973–1988		
					<i>By stage</i>		
					Local/regional	66.3	
					Distant	36.7	
					Unstaged	7.5	
					1989–1998		
					Local/regional	141.1	2.13
					Distant	28.6	0.78
					Unstaged	24.1	3.21
					Overall		
					Before PSA	110.6	
					During PSA	193.8	1.75
					<i>New Mexico</i>		
					1973–1988		
					<54	3.5	
					55–64	257.7	
					65–74	475.5	
					>75	1195.4	
					1989–1998		
					<54	6.7	1.91
					55–64	295	1.14
					65–74	1093.7	2.3
					>75	978.3	0.82

Table C29. Geographic variations in prostate cancer screening, incidence, and mortality (continued)

Reference Period Design	Population Data Source	Exposure Definitions	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate
					<i>1973–1988</i>	
					<i>By stage</i>	
					Local/regional	69.4
					Distant	22.6
					Unstaged	8.4
					<i>1989–1998</i>	
					Local/regional	115.9
					Distant	15.2
					Unstaged	5
					Overall	
					Before PSA	100.4
					During PSA	136.1
					Connecticut	
					<i>Age adjusted mortality</i>	
					1979–1986	78.2 (65.9–90.6)
					1987–1990	81.2 (65.1–97.3)
					1991–1998	93.1 (82.3–103.8)
					Iowa	
					1979–1986	79.5 (55.1–103.9)
					1987–1990	111.1 (71.9–150.3)
					1991–1998	93.5 (69.1–117.9)
					New Mexico	
					1979–1986	104.7 (69.4–140.0)
					1987–1990	62.1 (26.9–97.4)
					1991–1998	47.6 (29.6–65.5)
Lu-Yao, 2002 ¹⁰⁷	215,521 males	Geographical variations in the detection and treatment of prostate cancer	Prostate cancer mortality, incidence, and screening intensity (prostate biopsies and PSA)	Poisson distribution <i>Unit: patients</i>	Seattle Connecticut	<i>PSA rate ratio</i> 5.39 (4.76-6.11) 1 (reference)
1987-1997	Medicare beneficiaries from the Seattle (94 900) and Connecticut (120,621) identified in the SEER database				Seattle Connecticut	<i>Biopsy rate ratio</i> 2.2 (1.81-2.68) 1 (reference)
Retrospective cohort				<i>Risk adjustment: age; race, area of residence, study year, and an age-race interaction</i>	Seattle Connecticut	Age adjusted mortality rate ratio 1.03 (0.95-1.11) 1 (reference)
Evidence II2B						
Quality: 0.78						

Table C30. Geographic variations in prostate cancer treatments

Reference Period Design	Population Data Source	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate		
Lu-Yao, 1994 ¹⁰²	White men 50-70 years old from 9 areas in SEER program (~10% of the U.S. population)	Age adjusted rate of radical prostatectomy; proportions of cases receiving radical prostatectomy or radiation as initial treatment	Regression analysis. Pearson correlation between the average rates of incidence and mortality for each SEER area;	Atlanta	Radical Prostatectomy (rate per 100,000)		
1983-1989					1983	1989	
Retrospective cohort	The National Center of Health Statistics		<i>Unit:</i> Patient	Connecticut	11.9	118.2	
Ecologic analysis				Detroit	7.3	43.4	
				Hawaii	16	61.2	
Evidence II2B				Iowa	17.9	83.6	
				Now Mexico	32	68.5	
Quality: 0.73				San Francisco	32.7	93.6	
				Seattle	13.6	94.4	
				Utah	54.6	224.4	
				% of prostate cancer cases receiving radical prostatectomy as initial treatment		52.6	118.8
				1983			1989
	Atlanta		5	32.3			
Connecticut		3.3	15.7				
Detroit		6.1	17.4				
Hawaii		7.3	16.8				
Iowa		12.3	19.6				
Now Mexico		11.8	25.7				
San Francisco		4.8	25.9				
Seattle		16	36.8				
Utah		16.6	31.6				
All areas		9.4	25.6				
% of prostate cancer cases receiving Radiation as initial treatment							
1983			1989				
Atlanta		35.3	23.7				
Connecticut		29.4	28.1				
Detroit		28.2	36.7				
Hawaii		24.6	31.6				
Iowa		19.3	29.2				
Now Mexico		25.2	30				
San Francisco		32.8	32.6				
Seattle		32.1	31.4				
Utah		30.2	19.9				
All areas		28.5	30.4				

Table C30. Geographic variations in prostate cancer treatments (continued)

Reference Period Design	Population Data Source	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate	
Lu-Yao, 1993 ¹⁰⁸	A 20% national sample of male Medicare beneficiaries	Age adjusted radical prostatectomy rates/100,000 males to 1990 Medicare population; age and race adjusted utilization rate ratios compared with U.S. rate of prostatectomy	Poisson regression <i>Unit: Patient</i>	New England Mid Atlantic South Atlantic	Utilization rate ratio and 95% CI	
1984-1990				East North Central	0.51	0.44-0.59
Retrospective cohort			<i>Risk adjustment:</i>	East North Central	0.5	0.44-0.56
Evidence II2B	The Prostate Patient Outcomes Research Team		age, race, temporal trends	West North Central	1.12	1.01-1.23
Quality: 0.85	10,598 radical prostatectomies			West North Central	0.84	0.75-0.92
				West North Central	0.99	0.88-1.12
				Mountain	1.15	1.03-1.28
				Pacific	0.99	0.89-1.1
				USA	1.49	1.33-1.67
					1.76	1.6-1.95
					1 (reference)	
Mushinski, 1994 ¹⁰⁹	Claims data from Metropolitan Life Insurance Company, Corporate Health Strategies, Inc. Analyses	The total average hospital and physician charges; average length of stay in hospitals	ANOVA test <i>Unit: Patient</i>	USA	Cost \$	Length of stay in days
1994			<i>Risk adjustment: NR</i>	New England	18,680	5.56
Cross-sectional				Mid-Atlantic	18,500	5.3
Evidence III	1,004 radical prostatectomies			East North Central	20,610	6.71
Quality: 0.78				West North Central	18,100	5.63
				South Atlantic	17,700	5.17
				East South Central	18,940	5.75
				West South Central	12,910	5.62
				Mountain	18,900	5.52
				Pacific	16,220	4.92
					20,790	4.93
Mettlin et al, 1998 ¹¹⁰	The National Cancer Data Base Data from 1,114 hospitals on 103,979 patients diagnosed with prostate carcinoma in 1992 and from 1,144 hospitals on 72,337 patients diagnosed in 1995	Proportion of patients treated by radical prostatectomy and external beam radiation	Logistic regression <i>Unit Patient</i>		% of patients treated by radical prostatectomy	
1994					1992	1995
Retrospective cohort			<i>Risk adjustment:</i>	Northeast	22.4	27.5
Evidence II2B			age, race, American	Southeast	30.6	32.8
Quality: 0.83			Joint Committee on	Midwest	31.3	34.9
			Cancer stage, and	South	33.7	38.9
			tumor histologic	Mountain	37.3	40.4
			grade	Pacific	39.4	39.7
					% of patients treated by external beam radiation	
					1992	1995
				Northeast	37.5	31.1
				Southeast	33.8	28.4
				Midwest	29.1	23.8
				South	25.5	25.4
				Mountain	23.4	20.6
				Pacific	26.2	21.8

Table C30. Geographic variations in prostate cancer treatments (continued)

Reference Period Design	Population Data Source	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate	
Krupski et al, 2005 ¹¹ 1995-1999 Retrospective cohort Evidence II2B Quality: 0.63	104,316 men with localized/regional prostate cancer; 34,763 underwent surgical resection, 1,549 received postprostatectomy radiotherapy The National Cancer Institute's Surveillance Epidemiology and End Results (SEER)	Proportion of patients who received adjuvant radiation therapy after surgical resection of the prostate gland	Logistic regression <i>Unit Patient</i> <i>Risk adjustment:</i> patient age, race, grade of cancer 2000 Census median education and income level in the county of residence and ethnicity	Connecticut	% of patients treated by adjuvant therapy 9.5	
				Hawaii	3.9	
				Iowa	10	
				New Mexico	3	
				Utah	3.5	
				Detroit	6.2	
				San Francisco	10.2	
				Atlanta	5.8	
				Seattle	15.3	
				Los Angeles	25.2	
				San Jose-Monterey	7.4	
					Adjusted odds ratio of adjuvant therapy	
				Connecticut	1.21	0.98-1.4
				Hawaii	1.69	1.2-2.3
				Iowa	1.14	0.91-1.4
New Mexico	0.64	0.45- 0.89				
Utah	0.57	0.42- 0.76				
Detroit	0.46	0.36-0.59				
San Francisco	1.04	0.83-1.3				
Atlanta	0.9	0.7-1.1				
Seattle	1.38	1.1-1.6				
Los Angeles	1 reference					
San Jose-Monterey	1.21	0.95-1.5				

Table C30. Geographic variations in prostate cancer treatments (continued)

Reference Period Design	Population Data Source	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate
Cooperberg et al, 2003 ¹¹² 1989-2001 Retrospective cohort Evidence II2B Quality: 0.88	3,439 of patients diagnosed with prostate cancer since 1989 treated with radical prostatectomy, radiation therapy, or primary androgen deprivation therapy; CaPSURE database	proportion of patients treated by radical prostatectomy, external beam radiation, brachytherapy, watchful waiting, primary androgen deprivation therapy, and neoadjuvant androgen deprivation therapy	Logistic regression <i>Unit Patient</i> <i>Risk adjustment:</i> patient age, ethnicity, location, type of insurance, educational level, and income		% of patients treated by watchful waiting
				West	15.5
				East	8.85
				Midwest	12.5
				South	7.9
					% of patients treated by radical prostatectomy
				West	38.6
				East	50.9
				Midwest	44.6
				South	43.4
					% of patients treated by external beam radiation
				West	13.7
				East	22.04
				Midwest	17.8
				South	14.54
					% of patients treated by Brachytherapy
				West	5.3
				East	2.83
Midwest	6.93				
South	7.99				
	Adjusted odds ratio of primary androgen deprivation				
West	1.0 (reference)				
East	0.4 (0.3-0.5)				
Midwest	0.5 (0.3-0.7)				
South	0.8 (0.6-1.2)				
	Adjusted odds ratio of neoadjuvant androgen deprivation				
West	1.0 (reference)				
East	0.6 (0.4-.)				
Midwest	1.1 (0.7-.6)				
South	0.7 (0.5-.0)				

Table C30. Geographic variations in prostate cancer treatments (continued)

Reference Period Design	Population Data Source	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate							
Lai et al., 2001 ¹¹³	66,293 patients with localized prostate cancer who underwent radical prostatectomy from 1983 through 1992; the Surveillance, Epidemiology, and End Results Program (SEER)	Overall and disease-specific survival	A proportional hazards model		% of patients treated by radical prostatectomy							
1983-1992					Unit Patient	San Francisco	18.3					
Retrospective cohort					Evidence II2B	Quality: 0.85	Risk adjustment: age at diagnosis, year of diagnosis, marital status, tumor grade, and race/ethnicity	Connecticut	10			
								Detroit	14.1			
								Hawaii	14.6			
								Iowa	12.9			
								New Mexico	17.6			
								Seattle	24.2			
								Utah	31.4			
								Atlanta	16.7			
								<i>Overall survival in patients treated with prostatectomy</i>				
								San Francisco	1.02 (0.89–1.16)			
								Connecticut	0.85 (0.70–1.04)			
								Detroit	1.11 (0.98–1.26)			
Hawaii					0.85 (0.65–1.26)							
Iowa					0.99 (0.86–1.15)							
New Mexico					1.01 (0.85–1.20)							
Utah					1.11 (0.97–1.27)							
Atlanta					0.97 (0.79–1.19)							
<i>Disease-specific survival in patients treated with prostatectomy</i>												
San Francisco	1.17 (0.86–1.60)											
Connecticut	0.86 (0.52–1.41)											
Detroit	1.25 (0.93–1.70)											
Hawaii	1.18 (0.65–2.14)											
Iowa	1.16 (0.83–1.63)											
New Mexico	0.99 (0.64–1.52)											
Utah	0.84 (0.57–1.23)											
Atlanta	0.78 (0.44–1.38)											
Bubolz et al., 2001 ¹¹⁴	49,978 men treated with radical prostatectomy; 20% of the national sample	Case rates of radical prostatectomy (among total discharges); population-based rates of radical prostatectomy (among all eligible men in Medicare beneficiaries regardless of	Logistic regression	Unit Patient	Rates of radical prostatectomy as a % of U.S. rate							
1984 to 1997					1984-1989							
Retrospective cohort					Evidence II2B	Quality: 0.8	Risk adjustment: patient co morbidity; standardized to age distribution of the Medicare male beneficiaries in 1997	USA	1			
								New England	0.65			
								Middle Atlantic	0.5			
								East North Central	0.825			
								West North Central	1.19			
								South Atlantic	1.2			
								East South Central	0.96			
								West South Central	1			

Table C30. Geographic variations in prostate cancer treatments (continued)

Reference Period Design	Population Data Source	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate	
		whether they received treatment)		Pacific	1.68	
				USA	1990-1993	
				New England	1	
				Middle Atlantic	0.6	
				East North Central	0.62	
				West North Central	0.9	
				South Atlantic	1.22	
				East South Central	1.11	
				West South Central	0.96	
				Pacific	1	
					1.45	
					1994-1997	
				USA	1	
				New England	0.79	
				Middle Atlantic	0.78	
				East North Central	0.999	
				West North Central	1.275	
				South Atlantic	1.04	
				East South Central	0.96	
				West South Central	1.19	
				Pacific	1.1	
Cooperberg et al, 2004 ¹¹⁵	2,078 men diagnosed with low risk prostate cancer	Proportion of patients receiving primary treatment alternatives: radical prostatectomy , external-beam radiotherapy, interstitial radiotherapy (brachytherapy), primary androgen deprivation therapy , watchful waiting, and neoadjuvant androgen deprivation therapy	Logistic regression <i>Unit Patient</i>	West	% of patient by primary treatment RP	Brachyth. 10.3
1989 to 2001				Northeast	48.2	8.8
Retrospective cohort	The Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE)		<i>Risk adjustment: patient age, ethnicity, income, education, insurance type</i>	Midwest	59	19
Evidence II2B				South	48.8	17.9
Quality: 0.85				West	EBRT	PADT
				Northeast	8.3	10.6
				Midwest	13.4	7
				South	6.2	9.6
					7.5	15
					Watchful waiting	
				West	22.6	
				Northeast	11.8	
				Midwest	7.9	
				South	10.8	

Table C30. Geographic variations in prostate cancer treatments (continued)

Reference Period Design	Population Data Source	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate
Saigal et al, 2002 ¹¹⁶	17,586 Medicare beneficiaries newly diagnosed with clinically localized prostate cancer	Proportion of patients received combination of radical prostatectomy and radiation therapy with tomography (CT), magnetic resonance imaging (MRI), or bone scans	Multivariate logistical regression		% of patients received RP with CT scan
1991 to 1996			<i>Unit Patient</i>	Midwest	52.9
Retrospective cohort				Northeast	56.5
Evidence II2B	Health Care Financing Administration database		<i>Risk adjustment:</i> Charlson index score, age group, race, geographic region, and year of diagnosis	South	46.5
Quality: 0.9	Random sample of 5% of all Medicare beneficiaries			West	42.1
					% of patients received RP with CT scan
				Midwest	1.5
				Northeast	3
				South	2.9
				West	2.7
					% of patients received RP with bone scan
				Midwest	57.4
				Northeast	61
				South	57.7
				West	54.4
					% of patients received radiation therapy with CT
				Midwest	29.3
				Northeast	33.1
				South	20.2
				West	15.2
					% of patients received radiation therapy with MRI
				Midwest	1.1
				Northeast	2.6
				South	2
				West	1.8
					% of patients received radiation therapy with bone scan
				Midwest	54.7
				Northeast	57.7
				South	51.4
				West	48.1

Table C30. Geographic variations in prostate cancer treatments (continued)

Reference Period Design	Population Data Source	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate	
Wilt et al., 1999 ¹⁷ 1986-1996 Retrospective cohort Evidence II2B Quality: 0.9	13,398 men ages 45 to 84 years who underwent RP at a VAMC; the Department of Veterans Affairs Patient Treatment File and Outpatient Clinic File	RP utilization per 100,000 veteran users	Logistic regression <i>Unit Patient</i> <i>Risk adjustment: patient age and years of diagnosis</i>		Adjusted odds ratio of RP (95% CI)	
				Northeast	0.784	0.755; 0.814
				New England	0.725	0.67; 0.784
				Middle Atlantic	0.803	0.763; 0.846
				Midwest	1.117	1.085; 1.15
				East North Central	0.76	0.725; 0.797
				West North Central	1.7	1.63; 1.774
				South	1.028	1.001; 1.056
				South Atlantic	0.968	0.93; 1.008
				East South Central	1.012	0.952; 1.076
				West South Central	1.097	1.053; 1.148
				West	1.11	1.075; 1.146
				Mountain	1.141	1.079; 1.206
				Pacific	1.081	1.032; 1.132
				USA	1 (reference)	
					RP rate/100,000	
				Northeast	46.8	
				New England	43.7	
				Middle Atlantic	48.1	
				Midwest	67.1	
East North Central	46.1					
West North Central	102.1					
South	60.8					
South Atlantic	57.4					
East South Central	60.2					
West South Central	65.7					
West	64.3					
Mountain	68					
Pacific	62					
USA	60.5					
	Odds ratio of 30 days mortality after RP					
West	1	1-1				
Northeast	1.18	0.76; 1.81				
South	1.23	0.9; 1.69				
Midwest	1.06	0.74; 1.51				

Table C30. Geographic variations in prostate cancer treatments (continued)

Reference Period Design	Population Data Source	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate
Hu, 2003 ¹¹⁸	2,292 Medicare beneficiaries after radical prostatectomy	In-hospital complications; Means length of stay	Multiple regression <i>Unit: Patient</i>	Northeast South West Midwest	Adjusted odds ratio of in hospital complications after RP 1 1-1 1.05 0.76; 1.46 0.58 0.38; 0.88 0.86 0.62; 1.2
Retrospective cohort	Medicare claims data		<i>Risk adjustment: patient age, race, co morbidities, hospital type</i>	Northeast South West Midwest	Adjusted odds ratio of anastomatic stricture after RP 1 1 1 1.18 0.82 1.7 1.04 0.68 1.58 0.94 0.65 1.35
Evidence: II-2C				Northeast South West Midwest	Mean length of stay Reference -0.93 (-1.36; 0.5) -1.63 (-2.19; 1.07) -1.19 (-1.66; 0.72)
Quality: 0.86					
Litwin et al, 1998 ¹¹⁹	688,000 men Medicare beneficiaries treated with radical prostatectomy ; national 5% simple random sample from the Health Care Financing Administration	Radical prostatectomy rates per 100,000 male Medicare beneficiaries	Descriptive statistics and chi-square t <i>Unit Patient</i> <i>Risk adjustment: stratification by patient age and race</i>	USA 1991 USA 1992 USA 1993 Northeast 1991 Northeast 1992 Northeast 1993 South 1991 South 1992 South 1993 Midwest 1991 Midwest 1992 Midwest 1993 West 1991 West 1992 West 1993	Radical prostatectomy rates/100,000 216 284 235 136 206 151 223 305 250 233 290 241 295 346 313
Retrospective cohort					
Evidence: II-2C					
Quality: 0.78					

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Table C30. Geographic variations in prostate cancer treatments (continued)

Reference Period Design	Population Data Source	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate		
Escobedo, 2004 ¹⁰⁶	3,274 African American men in Connecticut, Iowa, and New Mexico diagnosed with localized or regional prostate cancer in 1979-1998 The National Center for Health Statistics (NCHS), SEER database	Prostate cancer treatment strategies: prostatectomy, transurethral resection of the prostate, radiation only, prostatectomy plus radiation, observation, and all other (diagnostic categories, non-cancer directed surgery, subtotal/simple prostatectomy, pelvic surgery, node surgery, radioactive implants, radioisotopes)	Poisson distribution. <i>Unit:</i> patients <i>Risk adjustment:</i> age; direct method of standardization to 1970 U.S. population	<i>Connecticut 1983–1988</i>	% of patients who received therapy		
1979-1998				Prostatectomy	6.6		
Retrospective cohort				Transurethral resection of the prostate	54.1		
Evidence II2B				Radiation only	0		
Quality: 0.75				Prostatectomy plus radiation	0.8		
				Observation	1.7		
				All other	36.8		
					<i>Connecticut 1989–1994</i>		
					Prostatectomy	21.3	
					Transurethral resection of the prostate	19.4	
		Radiation only	0.6				
		Prostatectomy plus radiation	2.7				
		Observation	1.3				
		All other	54.7				
			<i>Iowa 1983–1988</i>	1989–1994			
		Prostatectomy	11.1	25			
		Transurethral resection of the prostate	72.2	15.6			
		Radiation only	0	0			
		Prostatectomy plus radiation	0	9.4			
		Observation	1.9	1			
		All other	14.8	49			
			<i>New Mexico 1983–1988</i>	1989–1994			
		Prostatectomy	5.9	28.8			
		Transurethral resection of the prostate	55.9	15			
		Radiation only	0	0			
		Prostatectomy plus radiation	2.9	7.5			
		Observation	0	1.3			
		All other	35.3	47.5			

Table C30. Geographic variations in prostate cancer treatments (continued)

Reference Period Design	Population Data Source	Outcomes	Analysis/Unit	Exposure Categories	Outcome Rate
Brandeis, 2000 ¹²⁰	10,107 Medicare beneficiaries treated for early stage prostate carcinoma from inpatient, outpatient, and part B claims	Proportion of patients treated with Brachytherapy, external beam radiation therapy, radical prostatectomy, and its combinations	Descriptive statistic, chi-square test <i>Unit: patients</i>		<i>% of patients treated by Brachytherpay</i>
1991-1993				Midwest	2.3
Retrospective cohort	The Health Care Financing Administration		<i>Risk adjustment: comorbidity</i>	Northeast	4.8
Evidence: II-2C				South	5.7
Quality: 0.78				West	3.3
				Other	1.8
					<i>% of patients treated by Brachytherpay + external beam radiation therapy</i>
				Midwest	1
				Northeast	2.8
				South	3.1
				West	3.5
				Other	0
					<i>% of patients treated by radical prostatectomy</i>
				Midwest	33.2
				Northeast	23.1
				South	32.8
	West	44.2			
	Other	38.2			
		<i>% of patients treated by radical prostatectomy +external beam radiation therapy</i>			
	Midwest	3.9			
	Northeast	2.1			
	South	3.5			
	West	4			
	Other	1.8			
		<i>% of patients treated by external beam radiation therapy</i>			
	Midwest	59.7			
	Northeast	67.2			
	South	54.9			
	West	45.1			
	Other	58.2			

Table C31. Association between hospital volumes (radical prostatectomy) and surgery related mortality

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis/Units	Risk Adjustment	Volume Categories	Outcome Rate (%)	Adjusted Volume Effect
Ellison, 2000 ¹²¹	66,693 patients after prostatectomy; 1,334 hospitals	Nationwide Inpatient Sample database	In-hospital death after radical prostatectomy	Multiple logistic regression Unit :patient	Patient age and comorbidity	<i>Annual Hospital Volume (% hospitals)</i>		Odds ratio
1989-1996						<25 (76)	0.3	1.78 (1.2; 2.7)
Retrospective cohort						25-54 (17)	0.28	1.71 (1.2; 2.6)
Evidence: II-2C		Average number of procedures/year		Goodness-of-fit: Yes		>54 (7)	0.17	1 (reference)
Quality: 0.75				Discrimination: Not reported		<i>Subgroups by patient age</i>		
						>65 years		
						Volume		
						<25	0.4	
						25-54	0.38	
						>54	0.25	
						<65 years		
						Volume		
						<25	0.15	
						25-54	0.15	
						>54	0.5	
Begg,2002 ¹²²	11,522 Medicare beneficiaries (Parts A and B) after radical prostatectomy	SEER data base linked to Medicare claims.	Postoperative death within 30-60 days after radical prostatectomy	GEE-logistic regression Unit: Patient	Patient age, race, stage of cancer, comorbidities	<i>Annual Hospital Volume (% hospitals)</i>		30 days mortality
1992-1996						<16 (69)	0.5	
Retrospective cohort						17-28 (17)	0.5	
Evidence: II-2C		Average number of procedures/year		Goodness-of-fit: Not reported	Hospital - surgeon correlations	29-50 (9)	0.5	
Quality: 0.63	6,421 with localized PC					51-120 (5)	0.5	60 days mortality
	403 hospitals			Discrimination: Not reported		<16	0.6	
						17-28	0.6	
						29-50	0.6	
						51-120	0.5	

Table C31. Association between hospital volumes (radical prostatectomy) and surgery related mortality (continued)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis/Units	Risk Adjustment	Volume Categories	Outcome Rate (%)	Adjusted Volume Effect
Yao, 1999 ¹²³	101,604 Medicare beneficiaries after radical prostatectomy	Medicare claims data	Postoperative death within 30-90 days after radical prostatectomy	Logistic regression	Patient age, race, comorbidities; surgeon specialty, hospital teaching status	<i>Hospital Volume</i> <38 (9/year) 39- 74 (14/year) 75-140 (27/year) >141 (36/year)	0.63 0.59 0.56 0.39	1.51 (1.25; 1.77) 1.43 (1.17; 1.69) 1.42 (1.16; 1.68) 1 (reference)
Retrospective cohort		Number of procedures/time of the study		Unit: Patient				
Evidence: II-2C				Goodness-of-fit: Not reported				
Quality: 0.677				Discrimination: Not reported				
Wennberg, 1987 ¹²⁴	4,570 Medicare beneficiaries after prostatectomy	Medicare claims data: 16 hospitals	Postoperative death within 90 days after prostatectomy	Logistic regression	Patient age, comorbidities	<i>Annual Hospital Volume</i> <40 40-90 >91		1 (reference) 1.26 (0.69; 2.32) 1.66 (0.95; 2.89)
Retrospective cohort		Number of procedures/time of the study		Unit: Patient	Hospital size and teaching status			
Evidence: II-2C				Goodness-of-fit: Not reported				
Quality: 0.655				Discrimination: Not reported				

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Table C32. Association between hospital volumes (radical prostatectomy) and complications (cardiac, respiratory or vascular events, the need for reoperation, bleeding, renal failure, and shock)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis/Units	Risk Adjustment	Volume Categories	Outcome Rate (%)	Adjusted Volume Effect
Yao, 1999 ¹²³	101,604 Medicare beneficiaries after radical prostatectomy	Medicare claims data	In-hospital complications	Logistic regression	Patient age, race, comorbidities; surgeon specialty, hospital teaching status	<i>Hospital Volume</i> <38 (9/year) 39-4 (14/year) 75-140 (27/year) >141 (36/year)		Serious complications 1.4 3(1.37; 1.48) 1.25 (1.19; 1.31) 1.09 (1.03; 1.15) 1(reference)
1991-1994		Number of procedures/time of the study		Unit: Patient				
Retrospective cohort				Goodness-of-fit: Not reported			Any complications	
Evidence: II-2C				Discrimination: Not reported		<38 (9/year) 39- 4 (14/year) 75- 140 (27/year) >141 (36/year)	31.3(30.8-31.9) 28.7(28.2-29.3) 27.8(27.2-28.3) 26.3(25.8-26.9)	1.28 (1.24; 1.32) 1.13 (1.08; 1.17) 1.08 (1.04; 1.12) 1 (reference)
Quality: 0.677								
Hu, 2003 ¹¹⁸	2,292 Medicare beneficiaries after radical prostatectomy	Medicare claims data.	In-hospital complications	Multiple regression	Patient age, race, comorbidities, hospital type, region	<i>Hospital volume (% of procedures)</i> Low (85.2) (<60/year) High (14.8) (>60 /year)		Postoperative complications 1 (reference) 0.84(0.59; 1.19)
1997-1998		Number of procedures/time of the study		Unit: Patient			21.6 16.8	
Retrospective cohort				Goodness-of-fit: Not reported				
Evidence: II-2C				Discrimination: Yes				
Quality: 0.86								
Begg, 2002 ¹²²	11,522 Medicare beneficiaries (Parts A and B) after radical prostatectomy,	SEER data base linked to Medicare claims	Postoperative complications during 30 days after surgery	GEE-logistic regression	Patient age, race, stage of cancer, co morbidities; hospital - surgeon correlations	<i>Annual Hospital Volume (% hospitals)</i> <16 (69) 17-28 (17) 29-50 (9) 51-120 (5)		32 31 30 27
1992-1996		Average number of procedures/year		Unit: Patient				
Retrospective cohort				Goodness-of-fit: Not reported				
Evidence: II-2C				Discrimination: Not reported				
Quality: 0.63	6,421 with localized PC; 403 hospitals							

Table C33. Association between hospital volumes (radical prostatectomy) and quality measures (cancer control, late urinary complications, or long term incontinence, operative quality)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis/Units	Risk Adjustment	Volume Categories	Outcome Rate (%)	Adjusted Volume Effect
Ellison, 2000 ¹²⁵	12,635 Medicare beneficiaries after radical prostatectomy	SEER database	Style of cancer control: use of adjuvant therapy more than 6 months after radical prostatectomy	Cox model; Kaplan-Meier Unit: Patient	Patient age, histological grade, pathological stage, and comorbidity	<i>Annual Hospital Volume (%)</i> <16 (64) 17-28 (17) 29-50 (11) 51-120 (8)	Cancer control (Adjuvant therapy) 31.9 26.9 27.7 26.9	<i>Adjusted for tumor stage and grades</i> 1.24 (1.13; 1.37) 1.09 (0.99; .19) 1.02 (0.94; .12) 1 (reference)
Evidence: II-2C Quality: 0.745	5,837 with localized PC 348 hospitals	Number of procedures/time of the study		Goodness-of-fit: Yes Discrimination: Not reported				Adjusted for tumor stage and grades and patients co morbidities
						<16 17-28 29-50 51-120		1.25 (1.14; .38) 1.11 (1.01; .21) 1.03 (0.94; .12) 1 (reference)
Begg, 2002 ¹²²	11,522 Medicare beneficiaries (Parts A and B) after radical prostatectomy	SEER data base linked to Medicare claims	Late urinary complications from 30 to 365 days after radical prostatectomy	GEE-logistic regression Unit: Patient	Patient age, race, stage of cancer, comorbidities	<i>Annual Hospital Volume (%)</i> <16 (69) 17-28 (17) 29-50 (9) 51-120 (5)	Late urinary complications (events) 18 19 16 13	
Evidence: II-2C Quality: 0.63	6,421 with localized PC; 403 hospitals	Average number of procedures/year	Long term incontinence	Goodness-of-fit: Not reported Discrimination: Not reported	Hospital - surgeon correlations		Late urinary complications (symptoms) 28 29 23 20	
						<16 17-28 29-50		6.5 6.4 7

Table C33. Association between hospital volumes (radical prostatectomy) and quality measures (cancer control, late urinary complications, or long term incontinence, operative quality) (continued)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis/Units	Risk Adjustment	Volume Categories	Outcome Rate (%)	Adjusted Volume Effect
						51-120	7.6	
						<16	19	
						17-28	19	
						29-50	18	
						51-120	18	
Hu, 2003 ¹¹⁸ 1997-1998 Retrospective cohort	2,292 Medicare beneficiaries after radical prostatectomy	Medicare claims data Number of procedures/time of the study	Late urinary complications 12 months after radical prostatectomy	Multiple regression Unit: Patient	Patient age, race, comorbidities, hospital type, region	<i>Hospital volume(% of procedures)</i> Low (85.2) (<60/year) High (14.8) (>60/year)	Late urinary complications (events) 26.8 19.8	1 (reference) 0.72 (0.49; 1.04)
								Evidence: II-2C Quality: 0.86
Imperato, 2000 ¹²⁶ 1996 Cross-sectional	583 Medicare beneficiaries living in New York State after radical prostatectomy 113 hospitals	Medicare claims data Number of procedures/time of the study	Operative quality indicators	Chi square – test Unit: Patient	Not applicable	<i>Hospital volume (% hospitals)</i> 1-4 (67) 5-9 (22) >10 (10)	Scores of Operative quality indicators 49.1 47.6 58.4	
								Evidence: III Quality:0.52

Table C34. Association between hospital volumes (radical prostatectomy) and length of stay in the hospital

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis Units	Risk Adjustment	Volume Categories	LOS (Days)	Adjusted Volume Effect
Ellison, 2000 ¹²⁵ 1989-1996 Retrospective cohort Evidence: II-2C Quality: 0.75	66,693 patients after prostatectomy	Nationwide Inpatient sample database Average number of procedures/year	Length of stay	Multiple logistic regression Unit :patient Goodness-of-fit: Yes Discrimination: Not reported	Patient age and comorbidity	<i>Annual hospital volume</i> <25 25-54 >54 <i>Annual hospital volume</i> <25 25-54 >54	Mean (median) 5.4 (5) 4.8 (4) 4.2 (4) Hospital charges \$15,600 \$15,100 \$13,500	Odds ratio
Yao, 1999 ¹²³ 1991-1994 Retrospective cohort Evidence: II-2C Quality: 0.677	101,604 Medicare beneficiaries after radical prostatectomy	Medicare claims data Number of procedures/time of the study	Length of stay Changes in length of stay from 1991 to 1994 Readmission in 30 days	Logistic regression Unit: Patient Goodness-of-fit: Not reported Discrimination: Not reported	Patient age, race, comorbidities; surgeon specialty, hospital teaching status	<i>Hospital volume (annual median)</i> Low <38(9) Medium-low 39-4 (14) Medium-high 75- 140 (27) High 141(36) <i>Increase in volume (1991-1994)</i> Low Medium-low Medium-High High <i>Unchanged volume</i> Low Medium-low Medium-high High	Mean (95% CI) 8.51 (8.47; 8.56) 8.18 (8.14; 8.22) 7.7 (7.66; 7.74) 7.81 (7.77; 7.85) 1.62 (1.33; 1.91) 1.42 (1.18; 1.67) 1.5 (1.29; 1.72) 1.49 (1.27; 1.7) 1.34 (1.12; 1.57) 1.38 (1.21; 1.55) 1.29 (1.12; 1.47) 1.37	

Table C34. Association between hospital volumes (radical prostatectomy) and length of stay in the hospital (continued)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis Units	Risk Adjustment	Volume Categories	LOS (Days)	Adjusted Volume Effect
						<i>Decreased Volume</i>	(1.17; 1.57)	
						Low	0.9 (0.63; 1.17)	
						Medium-low	1.07 (0.89; 1.24)	
						Medium-high	1.19 (1.02; 1.36)	
						High	1.2 4 (0.93; 1.55)	
						<i>Hospital volume</i>		<i>Readmission</i>
						Low		1.3 (1.21; 1.39)
						Medium-low		1.16 (1.07; 1.25)
						Medium-high		1.08 (0.99; 1.17)
						High		1 (Reference)
Hu, 2003 ¹¹⁸	2,292 Medicare beneficiaries after radical prostatectomy	Medicare claims data Number of procedures/time of the study	Length of stay	Multiple regression Unit: Patient Goodness-of-fit: Not reported	Patient age, race, comorbidities, hospital type, region	<i>Hospital volume</i> Low (<60/year) High (>60 /year)	LOS Mean (SD) 5.2 (3.8) 4.4 (2.1)	<i>Regression coefficient for mean LOS</i> 1 -0.42 (-0.89; 0.05)
Evidence: II-2C								
Quality: 0.86				Discrimination: Not reported				

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Table C35. Association between hospital status and outcomes

Reference Period Design	Population	Data Source Status Definition	Outcome	Analysis Units	Risk Adjustment	Status Categories	Crude Outcomes Rates	Adjusted Status Effect
Wennberg, 1987 ¹²⁴ 1974-1977 Retrospective cohort Evidence: II-2C Quality: 0.655	4,570 Medicare beneficiaries after prostatectomy	Medicare claims data 16 hospitals Presence of the teaching programs	Postoperative death within 90 days after prostatectomy	Logistic regression Unit: Patient Goodness-of-fit: Not reported Discrimination: Not reported	Patient age, comorbidities, hospital size and teaching status	Hospital status No teaching programs Teaching hospitals		Surgery related mortality 1.10 (0.69; 1.76) 1
Karakiewicz, 1998 ¹²⁷ 1988-1996 Retrospective cohort Evidence: II-2C Quality: 0.6	4,997 beneficiaries of the Quebec Healthcare Plan after radical retropubic prostatectomy, assumed all with localized PC 104 urologists	Quebec Healthcare Plan database (insurance plane in the province of Quebec). Affiliation with academic center	Postoperative death within 30 days after radical prostatectomy Cumulative survival (31 months)	Cox proportional hazards regression model Unit: Patient Goodness-of-fit: Not reported Discrimination: Not reported	Patient age, physician age and volume, hospital type	Hospital affiliated with academic centers Nonacademic institutions	30 days mortality 0.45 0.72	
Gheiler, 1999 ¹²⁸ 1990-1996 Descriptive baseline analysis of planned implementation of clinical pathway Evidence: III Quality: 0.46	1,129 patients after radical prostatectomy Single hospital study 24 urologists	Records of all patients admitted to the hospital in 1990-1996 before and after implementation of clinical care pathway Urologists affiliated with academic center Private urologists	Average hospital stay	ANOVA test, Chi square test Goodness-of-fit: Not reported Discrimination: Not reported	NR	Urologists affiliated with academic center Private urologists	LOS in days 9 13	

Table C35. Association between hospital status and outcomes (continued)

Reference Period Design	Population	Data Source Status Definition	Outcome	Analysis Units	Risk Adjustment	Status Categories	Crude Outcomes Rates	Adjusted Status Effect	
Hu, 2003 ¹¹⁸ 1997-1998 Retrospective cohort Evidence: II-2C Quality: 0.86	2,292 Medicare beneficiaries after radical prostatectomy	Medicare claims data.	Late urinary complications 12 months after radical prostatectomy	Multiple regression	Patient age, race, comorbidities, hospital type, region	Hospital status		In hospital complications	
						Academic affiliation		1.0 (0.8; 1.37)	
		Government hospitals vs. nonprofit institutions	Anastomotic stricture	Goodness-of-fit: Not reported	Discrimination: Yes		Nonacademic		1
							Academic affiliation		1.1 (0.83; 1.46)
			Length of stay				Nonacademic		1
							Academic affiliation		Reduction in LOS 0.03 (0.39; 0.34)
							Government Hospitals vs. Nonprofit		In hospital complications 1.32 (0.96; 1.82)
							Government Hospitals vs. Nonprofit		Anastomotic stricture 1.45 (1.03; 2.04)
					Government Hospitals vs. nonprofit		Increase in LOS 0.51 (0.04; 0.98)		

Table C35. Association between hospital status and outcomes (continued)

Reference Period Design	Population	Data Source Status Definition	Outcome	Analysis Units	Risk Adjustment	Status Categories	Crude Outcomes Rates	Adjusted Status Effect	
Gaylis, 1998 ¹²⁹	116 patients after radical retropubic prostatectomy; two hospitals study	Records of all patients admitted to hospitals in 1990-1996	Length of stay	T-test	Not reported	Hospital status	Cost 1990-1995		
1990-1996				Unit patient		Not for profit	\$17,743		
Case-series				Goodness-of-fit: Not reported		For profit	\$24,481		
Evidence: III				Hospitals ownership: profit and not-for-profit		Not for profit	1996	\$13,233	
Quality: 0.41				Discrimination: Not reported		For profit	\$25,979		
Yuan, 2000 ¹³⁰	17,260 Medicare beneficiaries after prostatectomy	The Health Care Financing Administration (HCFA) database	30-day mortality	Multiple regression	Year of admission, patient age and race, and major comorbidities	Hospital status	30 day mortality	30 day mortality	
1984-1993				Unit patient		For profit	1.1		
Retrospective cohort				Goodness-of-fit: Yes		Not for profit	1		
						Public	1.2		
						Teaching not for profit	0.9		
Evidence: II-2C				Discrimination: Yes		Teaching public	0.9		
						For profit vs. Teaching not for profit		1.18 (1.1; 1.22)	
						Not for profit vs. Teaching not for profit		1.1 (1.05; 1.15)	
						Public vs. Teaching not		1.2 (1.15; 1.23)	
Quality: 0.7				Types of hospitals (American Hospital Association File): for-profit, not-for-profit, non teaching public, teaching not-for-profit, and teaching public hospitals					
	LOS	LOS							
	For profit	6.6							
	Not for profit	6.9							
	Public	6.4							
Teaching not for profit	7.9								

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Table C35. Association between hospital status and outcomes (continued)

Reference Period Design	Population	Data Source Status Definition	Outcome	Analysis Units	Risk Adjustment	Status Categories	Crude Outcomes Rates	Adjusted Status Effect
						Teaching public	8.2	
						For profit vs. teaching not for profit		0.875
						Not for profit vs. teaching not for profit		0.9
						Public vs. teaching not for profit		0.85
						Teaching public vs. teaching not for profit		1

Table C36. Association between surgeon volumes (radical prostatectomy) and surgery related mortality

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis Units	Risk Adjustment	Volume Categories	Crude Rate (%)	Adjusted Volume Effect
Begg, 2002 ¹²²	11,522 Medicare beneficiaries (Parts A and B) after radical prostatectomy	SEER data base linked to Medicare claims 403 hospitals Average number of procedures/year	Postoperative death within 30-60 days after radical prostatectomy	GEE logistic regression Unit: Patient	Patient age, race, stage of cancer, comorbidities; hospital-surgeon correlations	<i>Annual surgeon volume</i> (% surgeons) 1-4 (64) 5-9 (20) 10-15 (10) 16-58 (6) <i>Annual surgeon volume</i> 1-4 (64) 5-9 (20) 10-15 (10) 16-58 (6)	30 days Mortality 0.4 0.5 0.5 60 days Mortality 0.5 0.5 0.6 0.6	
Evidence: II-2C Quality: 0.63	6,421 with localized PC 999 surgeons			Goodness-of-fit: Not reported Discrimination: Not reported				
Karakiewicz, 1998 ¹²⁷	4,997 beneficiaries of the Quebec Healthcare Plan after radical retropubic prostatectomy, assumed all with localized PC 104 urologists	Quebec Healthcare Plan database (insurance plans in the province of Quebec) Number of procedures during the study	Postoperative death within 30 days after radical prostatectomy Cumulative survival (31 months)	Cox proportional hazards regression model Unit: Patient	Patient age, physician age and volume, hospital type	<i>Surgeon age/volume</i> 28-37/4 38-47/8 48-57/5 58-67/6 68-77/0.5 <i>Surgeon age/volume</i> 28-37/4 38-47/8 48-57/5 58-67/6 68-77/0.5	Adjusted 30 days mortality 0.28 0.45 0.57 0.99 0 Cumulative survival, % 97.2 92.2 91.7 87.3 0	
Evidence: II-2C Quality: 0.6				Goodness-of-fit: Not reported Discrimination: Not reported				

Table C36. Association between surgeon volumes (radical prostatectomy) and surgery related mortality (continued)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis Units	Risk Adjustment	Volume Categories	Crude Rate (%)	Adjusted Volume Effect
Bianco, 1999 ¹³¹ 1993-1996 Retrospective cohort	5,238 Medicare beneficiaries (Parts A and B) after radical prostatectomy	SEER data base linked to Medicare claims Number of procedures during the study	Postoperative death within 30-60 days after prostatectomy	Logistic regression Unit Patient Goodness-of-fit: Not reported	Patient age, cancer stage, comorbidities, hospital volume	<i>Surgeon volume</i> <i>20-121</i> <i>Annual average volume</i> <i>17</i>	60 days mortality 0.5	
Evidence: II-2C Quality:0.63	159 surgeons			Discrimination: Not reported				

Table C37. Association between surgeon volumes (radical prostatectomy) and complications (cardiac, respiratory or vascular events, the need for reoperation, bleeding, renal failure, and shock)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis Units	Risk Adjustment	Volume Categories	Crude Rate (%)	Adjusted Volume Effect
Begg, 2002 ¹²²	11,522 Medicare beneficiaries (Parts A and B) after radical prostatectomy	SEER data base linked to Medicare claims 403 hospitals	Postoperative complications during 30 days after surgery	GEE logistic regression Unit: Patient	Patient age, race, stage of cancer, comorbidities	<i>Annual surgeon volume (% surgeons)</i> 1-4 (64) 5-9 (20) 10-15 (10) 16-58 (6)	Postoperative complications 32 31 30 26	
Evidence: II-2C Quality: 0.63	6,421 with localized PC 999 surgeons	Average number of procedures/year		Goodness-of-fit: Not reported Discrimination: Not reported	Hospital - surgeon correlations			
Hu, 2002 ¹¹⁸	2,292 Medicare beneficiaries after radical prostatectomy	Medicare claims data Number of procedures/time of the study	Postoperative in hospital complications	Multiple regression Unit: Patient	Patient age, race, comorbidities, hospital type, region	<i>Surgeon volume (% of procedures)</i> Low (92.2) (<40/year) High (7.8) (>40 /year) <i>Subgroups by hospital/surgeon volume</i> Low-low High-low Low-high High-high	Postoperative complications 21.9 11.8 22.4 18.6 13.6 10.5	1 (reference) 0.53 (0.32; 0.89)
Evidence: II-2C Quality: 0.86				Goodness-of-fit: Not reported Discrimination: Yes				

Table C37. Association between surgeon volumes (radical prostatectomy) and complications (cardiac, respiratory or vascular events, the need for reoperation, bleeding, renal failure, and shock) (continued)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis Units	Risk Adjustment	Volume Categories	Crude Rate (%)	Adjusted Volume Effect
Bianco, 1999 ¹³¹ 1993-1996 Retrospective cohort Evidence: II-2C Quality: 0.63	5,238 Medicare beneficiaries (Parts A and B) after radical prostatectomy 159 surgeons	SEER data base linked to Medicare claims Number of procedures/ time of the study	Postoperative in-hospital complications Variability in outcome among high volume surgeons	Logistic regression Unit Patient Goodness-of-fit: Not reported Discrimination: Not reported	Patient age, cancer stage, comorbidities, hospital volume	Surgeon volume 20-121 Annual average volume = 17 4 surgeons 12 surgeons Annual average volume = 17 Annual average volume = 17	Postoperative complications 28.6 <15 >50 Late urinary complication 25.2 Long term urinary complications 6.7	
Dash, 2004 ¹³² 1994-2000 Prospective cohort Evidence: II -2B Quality: 0.69	1,123 patients after radical retropubic prostatectomy Single academic center; 9 surgeons	Consecutive cases prospectively enrolled in the IRB approved study Average number of procedures/ year	Surgery related blood transfusion	Logistic regression Unit Patient Goodness-of-fit: Not reported Discrimination: Not reported	Patient age, race, hormone therapy use, clinical stage and grade, and prostate size; type of anesthesia	Annual surgeon Volume (% of patients) >15/year (94) <15/year (6)	Homologous transfusion rate 3 18.2 (range 0-20.6)	1 8.63 (3.95; 18.86)
Litwiller, 1995 ¹³³ 1984-1994 Design: Retrospective analysis of cases Evidence: III Quality: 0.47	428 patients after radical retropubic prostatectomy Single academic center; 18 surgeons	Records of all patients admitted to the hospital from 1984-1994; number of procedures performed by surgeon / study period	Surgery related blood loss and transfusion	Linear regression Goodness-of-fit: Not reported Discrimination: Not reported	Patient age, stage of cancer, comorbidities	Average surgeon volume 3 procedures (rank 1-9) Correlation with blood loss Correlation with transfusion	Average blood loss 1,327 ml -0.31 (Not significant) Average blood transfusions 1.57U -0.37 (Not significant)	

Table C38. Association between surgeon volumes (radical prostatectomy) and quality measures (late urinary complications or long term incontinence and operative quality)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis Units	Risk Adjustment	Volume Categories	Crude Rate (%)	Adjusted Volume Effect
Begg, 2002 ¹²²	11,522 Medicare beneficiaries (Parts A and B) after radical prostatectomy	SEER data base linked to Medicare claims 403 hospitals	Late urinary complications from 30 to 365 days after radical prostatectomy	GEE logistic regression Unit: Patient	Patient age, race, stage of cancer, comorbidities	<i>Annual surgeon volume (% surgeons)</i> 1-4 (64) 5-9 (20) 10-15 (10) 16-58 (6)	Late urinary complications (events) 19 18 17 14	
Evidence: II-2C Quality: 0.63	6,421 with localized PC 999 surgeons	Average number of procedures/year	Long term incontinence	Goodness-of-fit: Not reported Discrimination: Not reported	Hospital - surgeon correlations		Late urinary complications (symptoms) 28 26 27 20 Long term incontinence (events) 7.3 7.2 6.7 6.6 Long term incontinence (symptoms) 20 20 19 16	
						1-4 (64) 5-9 (20) 10-15 (10) 16-58 (6)		
						1-4 (64) 5-9 (20) 10-15 (10) 16-58 (6)		

Table C38. Association between surgeon volumes (radical prostatectomy) and quality measures (late urinary complications or long term incontinence and operative quality) (continued)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis Units	Risk Adjustment	Volume Categories	Crude Rate (%)	Adjusted Volume Effect
Hu, 2003 ¹¹⁸ 1997-1998 Retrospective cohort Evidence: II-2C Quality: 0.86	2,292 Medicare beneficiaries after radical prostatectomy	Medicare claims data Number of procedures/time of the study	Late urinary complications (anastomotic strictures) 12 months after surgery	Multiple regression Unit: Patient Goodness-of-fit: Not reported Discrimination: Yes	Patient age, race, comorbidities, hospital type, region	<i>Surgeon volume (% of procedures)</i> <40/year (92.2) >40/years (7.8) <i>Subgroups by hospital/ surgeon volume</i> Low-low High-low Low-high High-high	Anastomotic stricture 27.7 22 28.4 22.7 29.6 17.7	
Bianco, 1999 ¹³¹ 1993-1996 Retrospective cohort Evidence: II-2C Quality: 0.63	5,238 Medicare beneficiaries (Parts A and B) after radical prostatectomy 159 surgeons	SEER data base linked to Medicare claims Number of procedures/time of the study	Late urinary complications within 30 days-1 year after surgery Long term incontinence Variability in outcomes among high volume surgeons	Logistic regression Unit: Patient Goodness-of-fit: Not reported Discrimination: Not reported	Patient age, cancer stage, comorbidities, hospital volume	<i>Surgeon volume</i> <i>20-121 (17/year)</i> <i>19 surgeons</i> <i>11 surgeons</i> <i>38 surgeons</i> <i>11 surgeons</i>	Late urinary complications 25.2 Long term incontinence 6.7 Late urinary complications <5 >55 Long-term incontinence <10 >40	
Eastham, 2003 ¹³⁴ 1983-2002 Retrospective analysis of cases Evidence: III Quality: 0.68	4,629 patients after radical prostatectomy Two large urban centers; 44 surgeons	Records of all patients admitted to hospitals from 1983-2002 Number of procedures performed by surgeon/study period	Positive surgical margins	Logistic regression Unit: Patient Goodness-of-fit: Not reported Discrimination: Not reported	Cancer clinical stage and grade; surgeon and institution	<i>Surgeon volume</i> <8 10-16 20-23 >50 <i>Increment</i> <i>1 procedure</i>	Positive surgical margins rate 14 10-48 12-48 12	Regression coefficient for positive surgical margins -0.0007 (SE0.0002) RR 0.99 (0.9996; 0.998)

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Table C38. Association between surgeon volumes (radical prostatectomy) and quality measures (late urinary complications or long term incontinence and operative quality) (continued)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis Units	Risk Adjustment	Volume Categories	Crude Rate (%)	Adjusted Volume Effect
Hernandez, 2005 ¹³⁵	204 patients after radical retropubic prostatectomy	Records of all patients admitted to the hospital from 1996-2002	Positive surgical margins	Chi square test Unit: Patient	Not reported	Surgeon volume (per year) 101 (16.83) 10,317.17)	Positive surgical margins rate 5.9 5.8	
1996-2002			Bundle spring	Goodness-of-fit: Not reported			Bundle nerve sparing Bilateral 84.2	
Retrospective analysis of cases	Single hospital study; 2 surgeons	Number of procedures/ time of study		Discrimination: Not reported		101 103	36.9 Unilateral 15.8	
Evidence: III						101 103	54.4 Both bundles excised 0	
Quality :0.69						101 103	8.7	

Table C39. Association between surgeon volumes (radical prostatectomy) and length of stay in the hospital

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis Units	Risk Adjustment	Volume Categories	Length of Stay (%)	Adjusted Volume Effect
Hu, 2003 ¹¹⁸ 1997-1998 Retrospective cohort Evidence: II-2C Quality: 0.86	2,292 Medicare beneficiaries after radical prostatectomy	Medicare claims data Number of procedures/time of the study	Average hospital stay	Multiple regression Unit: Patient Goodness-of-fit: Not reported Discrimination: Not reported	Patient age, race, comorbidities, hospital type, region	Surgeon volume (% of procedures) <40/year (92.2) >40/years (7.8) Subgroups by hospital/surgeon volume Low-low High-low Low-high High-high	LOS Mean (SD) 5.2 (3.7) 4.1 (2.6) 5.2 (3.8) 4.7 (3.5) 4.8 (3.7) 3.7 (1.1)	Regression coefficient for mean LOS -0.66 (-0.06; 1.26)
Litwiller, 1995 ¹³³ 1984-1994 Retrospective analysis of cases Evidence: III Quality: 0.47	428 patients after radical retropubic prostatectomy Single academic center; 18 surgeons	Records of all patients admitted to the hospital from 1984-1994 Number of procedures performed by surgeon/study period	Average hospital stay	Linear regression Goodness-of-fit: Not reported Discrimination: Not reported	Patient age, stage of cancer, comorbidities	Average surgeon volume 3 procedures (rank 1-9) Correlation LOS	Average hospital stay 7.71 (rank 3-24) -0.51	
Gheiler, 1999 ¹²⁸ 1990-1996 Descriptive baseline analysis of planned implementation of clinical pathway Evidence: III Quality: 0.46	1,129 patients after radical prostatectomy Single hospital study 24 urologists	Records of all patients admitted to the hospital from 1990-1996 before and after implementation of clinical care pathway; an average numbers of procedures performed annually by surgeons	Average hospital stay	ANOVA test, Chi square test Goodness-of-fit: Not reported Discrimination: Not reported	Not reported	Surgeon volume (% procedures) High (41) – 53/year Low (59) – 7/year	Average hospital stay (nights) 7.2 8.2	

Table C39. Association between surgeon volumes (radical prostatectomy) and length of stay in the hospital (continued)

Reference Period Design	Population	Data Source Volume Definition	Outcome	Analysis Units	Risk Adjustment	Volume Categories	Length of Stay (%)	Adjusted Volume Effect
Leibman, 1998 ¹³⁶ 1994-1997	856 patients after radical retropubic prostatectomy	Records of all patients admitted to the hospital from 1990-1996 before and after implementation of clinical care pathway; an average number of procedures performed annually by surgeons	Average hospital length of stay	T-test to compare outcomes between groups	Not reported	Annual surgeon volume (% procedures)	LOS in days, Median	
Descriptive baseline analysis of planned implementation of clinical pathway Evidence: III Quality: 0.46	Single hospital study; 24 surgeons		Average hospital charges	Goodness-of-fit: No Discrimination: No		<12/year (21)	5.8	
						>12/year (79)	5.3	Charges in 1994
						<12/year (21)	\$11,798	
						>12/year (79)	\$11,113	Charges from 1994-1997
						< 12/year (21)	\$10,208	
						>12/year (79)	\$9,388	

Table C40. Sampling sources of studies that evaluated associations between providers' volumes (radical prostatectomy) and patients' outcomes

Source	Author	Time	Size	Hospital Volume	Surgeon Volume	Mortality	Morbidity	Urinary Complications	Long term Incontinence	LOS	Operational Quality
Single hospital	Hernandez ¹³⁵	1996-2002	506		X						X
Single hospital	Dash ¹³²	1994-2000	1,123	X	X		X				
Single hospital	Litwiller ¹³³	1984-1994	428	X	X					X	
Single hospital	Leibman ¹³⁶	1994-1998	856		X					X	
Single hospital	Gheiler ¹²⁸	1990-1994	1,129		X					X	
SEER-Medicare	Bianco ¹³¹	1992-1996	5,238		X	X	X	X	X		
SEER-Medicare*	Ellison ¹²⁵	1990-2005	12,635	X			X				
SEER-Medicare*	Begg ¹²²	1992-1996	11,522	X	X	X	X	X	X		
Quebec Healthcare Plan	Karakiewicz ¹²⁷	1988-1996	4,997		X	X					
Nationwide inpatient sample	Ellison ¹²¹	1989-1995	66,693	X		X				X	
Multihospital study	Imperato ¹²⁶	1996	583	X							X
Multihospital study	Gaylis ¹²⁹	1990-1996	116	Type		X	X	X		X	
Multihospital study	Eastham ¹³⁴	1983-2002	6,542		X						X
Medicare	Yao ¹²³	1991-1997	10,1604	X		X	X			X	
Medicare	Wennberg ¹²⁴	1974-1977	4,570	X		X					
Medicare	Yuan ¹³⁰	1984-1993	17,260	Type		X				X	
Medicare	Hu ¹¹⁸	1997-1998	2,292	X	X		X	X		X	

LOS = length of stay

* Studies used the same data base at the same period of time but followup was different

Table C41. Sampling sources of studies that evaluated associations between provider's locations and patient outcomes

Author	Source	Time	Incidence	Incidence of Localized Cancer	Mortality	Cancer Specific Mortality	Standardized Rate of Treatments	Probability of Treatments	Probability of PSA	Complications	LOS
Cooperberg ¹¹²	CaPSURE*	1989-2001						X			
Cooperberg ¹¹⁵	CaPSURE*	1989-2001						X			
Lu-Yao ¹⁰⁸	Medicare	1990					X	X			
Bubolz ¹¹⁴	Medicare	1984-1989						X			
Saigal ¹¹⁶	Medicare	1991-1996						X			
Hu ¹¹⁸	Medicare	1997-1998								X	X
Litwin ¹¹⁹	Medicare	1991					X				
Brandeis ¹²⁰	Medicare	1993-1996						X			
Mushinski ¹⁰⁹	MetLife	1994									X
Mettlin ¹¹⁰	National Cancer Database	1992						X			
Jemal ¹⁰⁵	NCHS	1995-2000	X	X	X	X					
Jemal ¹⁰⁴	NCHS	1970-1989				X					
Lu-Yao ¹⁰²	SEER	1983	X				X	X			
Krupski ¹¹¹	SEER	1995-1999						X			
Lai ¹¹³	SEER	1983-1992			X	X		X			
Escobedo ¹⁰⁶	SEER	1989-1998	X	X		X		X			
Shaw ¹³⁷	SEER	1991-1998						X			
Kafadar ¹⁰³	State Cancer Control Map	1953-1972				X					
Wilt ¹¹⁷	VAMC	1986-1994			X		X	X			
CDC ¹³⁸	CDC	1999-2004	X			X			X		

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LOS = length of stay

* Studies used the same database at the same period of time, the second study evaluated the association between provider's location in interaction with patient's health insurance

Table C42. Studies that evaluated association between other provider’s factors (specialty, facility structure, awareness) and patient outcomes (no overlapping in samples detected)

Author	Source	Year	Provider’s Factors	Screening	Treatment	Cost	Survival	Complication	Operation Quality	Satisfaction
Kim ¹³⁹	Survey	2002	Specialty	X						
McNight ¹⁴⁰	Survey	1996	Specialty	X						
Fowler ¹⁴¹	Survey	1998	Specialty	X	X					
Shay ¹⁴²	Survey	2002	Specialty		X					
Plawker ¹⁴³	Survey	1997	Specialty	X						
Gee ¹⁴⁴	Survey	1995	Specialty		X					
Hanna ¹⁴⁵	Survey	2002	Specialty		X					
Salminen ¹⁴⁶	Survey	2004	Specialty		X					
McNaughton Collins ¹⁴⁷	Survey	2002	Specialty/location	X	X					
Fowler ¹⁴⁸	Survey	2000	Specialty		X					
Kramolowsky ¹⁴⁹	Multi hospital	1995	Education			X				
Kramolowsky ¹⁵⁰	Single hospital	1995	Education			X				
Diamond ¹⁵¹	The patterns of care study	1990	Facility structure				X	X		
Cazzaniga ¹⁵²	Survey	1998	Inter physician variability						X	
Van Poppel ¹⁵³	Survey	2001	Inter physician variability					X	X	
Votron ¹⁵⁴	Survey	2004	Inter physician variability		X					
Maliski ¹⁵⁵	Single hospital	2005	Facility structure					X		
Maliski ¹⁵⁶	IMPACT study	2004	Physician communication					X		X

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Table C43. Association between physician specialty and patient outcomes

Reference Design	Data Source Population	Analysis Risk Adjustment	Specialty	Outcomes	P Values
Kim, 2002 ¹³⁹ Internet-based survey	Members of the Academy of Family Physicians 381 primary care physicians in 3 states: 113 family physicians 238 general internists 11.76 years of practice	Chi-square test		Recommended <i>PC</i> screening for patient >50 years old	
		Logistic regression	Family physician General internist	DRE 87% 69%	<0.01
		Not reported	Family physician General internist	<i>PSA</i> screening 67% 40%	<0.01
			Family physician General internist	<i>Not PC screening for patient >60 years old</i> 10% 20%	0.01
			Family physician General internist	Do not use age as a criteria 51% 33%	<0.01
			Family physician General internist	<i>Recommendations for patients with PSA 4.1-10 ng/ml</i> Repeat <i>PSA</i> at 4-6 weeks 40 29	0.06
			Family physician General internist	Repeat <i>PSA</i> at 6-12 months 13 14	0.93
			Family physician General internist	Prostate ultrasound 5 7	0.48
			Family physician General internist	Referral to urologist 42 50	0.15
			Family physician General internist	Referral to radiation oncologist Yes (all patients) 10 14	
			Family physician General internist	Yes, poor surgical candidates 9 10	
			Family physician General internist	By patient's request 17 21	
			Family physician General internist	By urologist's request 88 78	

Table C43. Association between physician specialty and patient outcomes (continued)

Reference Design	Data Source Population	Analysis Risk Adjustment	Specialty	Outcomes	P Values
				Use of alternative therapies for prevention and management of PC	
			Family physician	15	
			General internist	7	
McNIGHT, 1996 ¹⁴⁰	Board certified physicians in three states	Chi-square test		<i>Screening practices</i>	
Survey	231 urologists and 205 family physicians	Not reported	Urologist	DRE	0.14
			Primary care physicians	99%	
	Urologists: 99% males; mean age 50 years		Urologist	98%	
	city of practice >100,000 - 55%		Primary care physicians	Age at initial DRE (mean)	<0.01
	Primary care physicians: 89% males; mean age 46 years; city of practice >100,000 - 28%		Urologist	45	
			Primary care physicians	43	
			Urologist	Median Interval for DRE (months)	
			Primary care physicians	12	
			Urologist	12	
			Primary care physicians	PSA	<0.01
			Urologist	98%	
			Primary care physicians	87%	
			Urologist	Age at initial PSA	
			Primary care physicians	49	
			Urologist	49	
			Primary care physicians	Median Interval for PSA (months)	
			Urologist	12	
			Primary care physicians	12	
			Urologist	Single best screening tool	
			Primary care physicians	69% PSA	
			Urologist	59% DRE	
			Primary care physicians	Screening for asymptomatic patients <age 50 with negative family history	
			Urologist	14%	<0.01
			Primary care physicians	29%	
			Urologist	Screening for patients age <40 with a positive family history	
			Primary care physicians	2%	<0.01
			Urologist	19%	
			Primary care physicians	<i>Strategy in positive tests</i>	
			Urologist	66% biopsy	
			Primary care physicians	55% referral	
			Urologist	Screening cessation	
			Primary care physicians	61%	<0.01
			Urologist	14%	
			Primary care physicians	Age for screening cessation	
			Urologist	79	
			Primary care physicians	79	

Table C43. Association between physician specialty and patient outcomes (continued)

Reference Design	Data Source Population	Analysis Risk Adjustment	Specialty	Outcomes	P Values			
Fowler, 1998 ¹⁴¹	Random sample of the American Medical Association Registry of Physicians	Chi-square test Not reported		<i>Use of PSA almost always for patients at age 40-49 years</i>				
Survey	444 primary care physicians 394 urologists Urologists: 99% males More than 90% if time devoted to clinical practice - 88% Solo practice - 31%; Single specialty group - 53%; Multi specialty group - 16% Primary care physicians: 84% males More than 90% if time devoted to clinical practice - 88% Solo practice - 35%; Single specialty group - 42%; Multi specialty group - 23%		Urologists	33%	Not significant			
			Primary care physicians	19%				
			Urologists	97%	<0.05			
			Primary care physicians	55%				
			Urologists	98%	Not significant			
			Primary care physicians	66%				
			Urologists	88%	Not significant			
			Primary care physicians	65%				
			Urologists	50%	Not significant			
			Primary care physicians	58%				
			Urologists	25%	Not significant			
			Primary care physicians	53%				
							<i>Referral to urologists for a biopsy if PSA 4-10ng/ml</i>	
						Urologists	81%	
						Primary care physicians	69%	
						Urologists	66%	
						Primary care physicians	67%	
						Urologists	33%	
			Primary care physicians	58%				
			Urologists	13%				
			Primary care physicians	52%				
			Urologists	3%				
			Primary care physicians	45%				
				<i>Perception which therapy is better</i>				
				Patients life expectancy >10 years				
				Radical PE				
			Urologist	98%				
			Primary care physicians	73%				
				External beam radiotherapy				
			Urologist	53%				

Table C43. Association between physician specialty and patient outcomes (continued)

Reference Design	Data Source Population	Analysis Risk Adjustment	Specialty	Outcomes	P Values
			Primary care physicians	67%	
				Patients life expectancy <10 years	
				Radical PE	
			Urologist	13%	
			Primary care physicians	13%	
				External beam radiotherapy	
			Urologist	36%	
			Primary care physicians	48%	
				Watchful waiting	
				Patients life expectancy <10 years	
			Urologist	Definitely 13%; probably 55%	
			Primary care physicians	Definitely 17%; probably 52%	
				Patients life expectancy >10 years	
			Urologist	Definitely 1%; probably 2%	
			Primary care physicians	Definitely 2%; probably 11%	
Shay ¹⁴² 2000	61 urologists after residency in single medical center	Descriptive statistic	Training in RPP	<i>Use of RPP</i>	
	Urologists practice:		Yes (86%)	41%	
	Private group 66%	Chi-square test	No	13%	0.12
	Solo 20%	Not reported	Intensity of training		
	Academic 7%		>10 RPP in residency	53%	
			<10 RPP	21%	0.03
				<i>Reasons of not using RPP</i>	
			Training in RPP	Length of operation	
			Yes (86%)	4%	
			No	25%	0.03
				Difficulty of operation	
			Yes (86%)	20%	
			No	25%	0.75
				Partner preference	
			Yes (86%)	28%	
			No	12.50%	0.35
				Concerns to preserve potency	
			Yes (86%)	12	
			No	0	0.3
				Inability to obtain lymph nodes	
			Yes (86%)	12%	
			No	0%	0.3
				<i>Use of RPP</i>	
			Practice		
			Private group 66%	29%	
			Solo 20%	50%	
			Academic 7%	100%	0.11

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Table C43. Association between physician specialty and patient outcomes (continued)

Reference Design	Data Source Population	Analysis Risk Adjustment	Specialty	Outcomes	P Values
Fowler, 2000 ¹⁴⁸	Random sample of physicians in the United States listed as urologists and radiation oncologists in the American Medical Association Registry of Physicians and practicing at least 20 hours per week	Chi-square test Not reported		<i>Recommending routine PSA for men in average risk of prostate cancer</i> Patient age 40-49 years	
Survey	504 urologists (response rate 64) 559 radiation oncologists (response rate 76)		Radiation oncologists Urologists	24% 25%	0.93
			Radiation oncologists Urologists	50-59 years 90% 96%	<0.01
			Radiation oncologists Urologists	60-69 years 98 98	0.92
			Radiation oncologists Urologists	70-74 years 95% 89%	<0.01
			Radiation oncologists Urologists	75-79 years 77% 51%	<0.01
			Radiation oncologists Urologists	>80 years 43% 16%	<0.01
				<i>Survival benefits of different treatments</i> Brachytherapy	
			Urologists Radiation oncologists	Baseline life expectancy <10 years 38% 35%	
			Urologists Radiation oncologists	Baseline life expectancy >10 years 66% 82%	
			Urologists Radiation oncologists	External beam radiation Baseline life expectancy <10 years 46% 39%	
			Urologists Radiation oncologists	Baseline life expectancy >10 years 67% 86%	
			Urologists Radiation oncologists	Radical prostatectomy Baseline life expectancy <10 years 14% 22%	
			Urologists Radiation oncologists	Baseline life expectancy >10 years 98% 79%	

Table C43. Association between physician specialty and patient outcomes (continued)

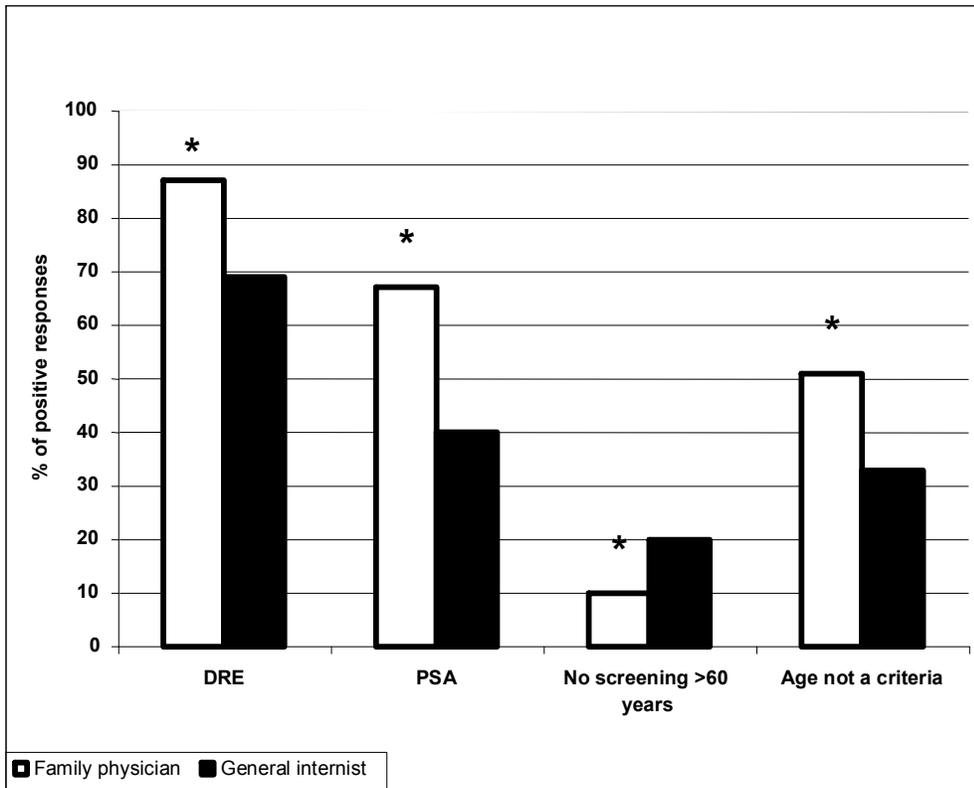
Reference Design	Data Source Population	Analysis Risk Adjustment	Specialty	Outcomes	P Values
				<i>Comparison of treatments benefits in patients with clinically localized PC and life expectancy <10 years</i>	
				Radiation is better compared with prostatectomy	
			Radiation oncologists	10%	
			Urologists	9%	<0.01
				Both therapy are the same	
			Radiation oncologists	68%	
			Urologists	40%	<0.01
				Prostatectomy better	
			Radiation oncologists	2%	
			Urologists	17%	<0.01
				Neither offer survival benefit	
			Radiation oncologists	19%	
			Urologists	32%	<0.01
				External beam radiation is better than radical prostatectomy	
			Radiation oncologists	3%	
			Urologists	0%	<0.01
				Both therapy are the same	
			Radiation oncologists	72%	
			Urologists	6%	<0.01
				Prostatectomy better	
			Radiation oncologists	20%	
			Urologists	93%	<0.01
				Neither offer survival benefit	
			Radiation oncologists	3%	
			Urologists	0%	<0.01
				Brachytherapy is better than External beam radiation	
			Radiation oncologists	21%	
			Urologists	30%	<0.01
				Both the same	
			Radiation oncologists	53%	
			Urologists	33%	<0.01
				Neither offer survival benefit	
			Radiation oncologists	2%	
			Urologists	4%	<0.01
				<i>Perceived rates of use the treatments for PC</i>	
				Radical prostatectomy overused	
			Radiation oncologists	82%	
			Urologists	34%	<0.01

Table C43. Association between physician specialty and patient outcomes (continued)

Reference Design	Data Source Population	Analysis Risk Adjustment	Specialty	Outcomes	P Values
			Radiation oncologists	Radical prostatectomy underused	
			Urologists	16%	
			Radiation oncologists	51%	<0.01
			Urologists	Use at about the right rate	
			Radiation oncologists	16%	
			Urologists	51%	<0.01
			Radiation oncologists	External beam radiation overused	
			Urologists	13%	
			Radiation oncologists	37%	<0.01
			Urologists	External beam radiation underused	
			Radiation oncologists	50%	
			Urologists	5%	<0.01
			Radiation oncologists	Use at about the right rate	
			Urologists	35%	
			Radiation oncologists	51%	<0.01
			Urologists	Brachytherapy overused	
			Radiation oncologists	26%	
			Urologists	30%	<0.01
			Radiation oncologists	Brachytherapy underused	
			Urologists	44%	
			Radiation oncologists	27%	<0.01
			Urologists	Use at about the right rate	
			Radiation oncologists	20%	
			Urologists	21%	<0.01
Vorton, 2004 ¹⁵⁴	676 participating in national meetings general practitioners	Logistic regression	Physician sex	<i>Referring elderly patient with PC to a specialist</i>	
			Males	Odds ratio 0.44	0.03
			Females	1	
Survey	546 completed questionnaire	Patient age, sex, comorbidity, physician characteristics	Ages physicians vs. young	<i>Non curative approach (hormone therapy and watchful waiting)</i>	
			Physician sex	Odds ratio 1.1 (1.02-1.09)	<0.01
			Physician place to work	Not significant	
			Physician age	Not significant	
			Physician sex	Not significant	
			Physician place to work	Not significant	
				<i>Treatments of prostate cancer in elderly patients</i>	
				Surgical treatment vs. Hormone therapy	

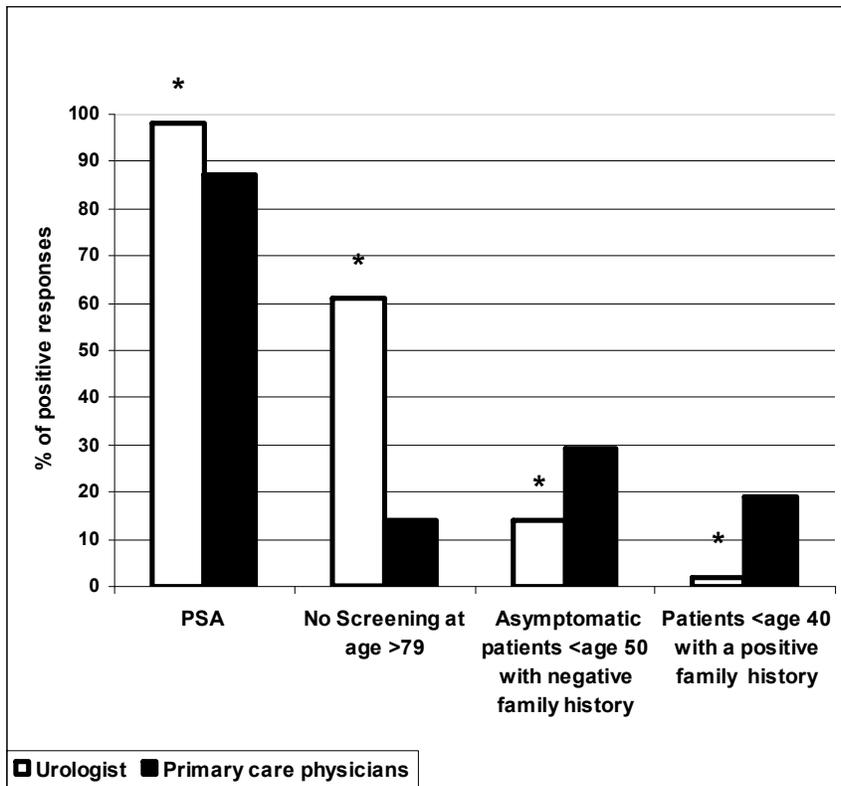
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Figure C7. Percentage of responses by family physicians and general internists to the question: "Do you recommend the following for prostate cancer screening for patients 50 years old and older?" (Kim, 2002)¹³⁹



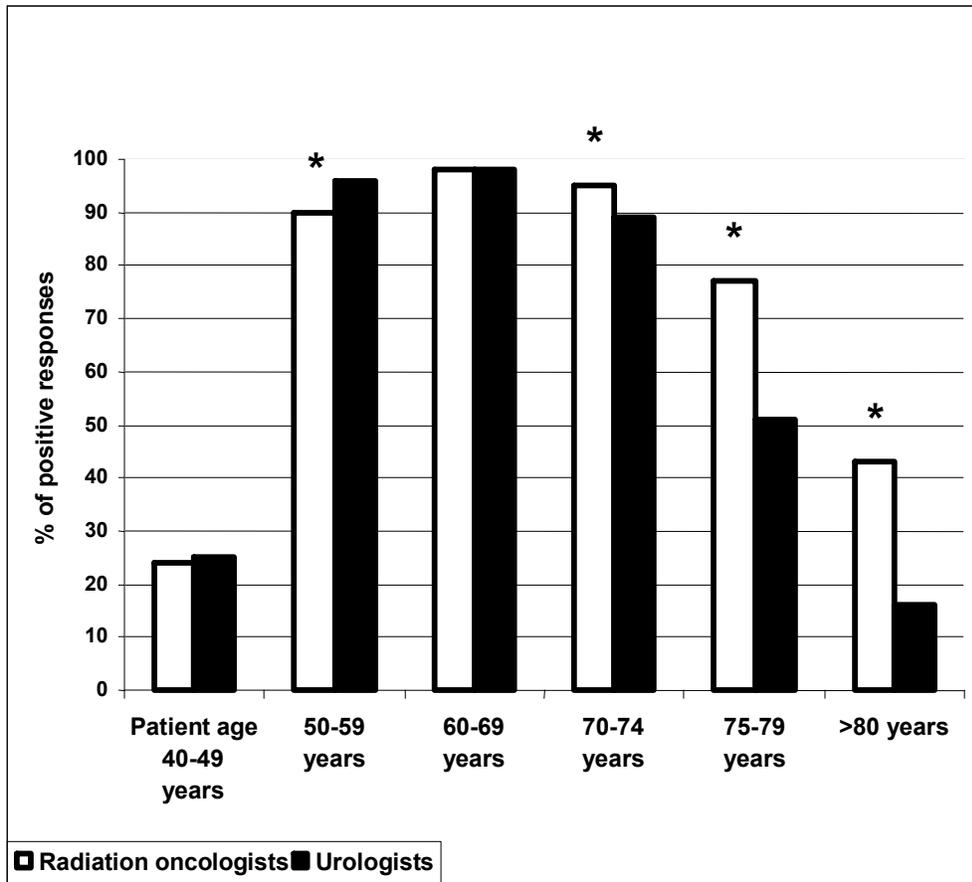
DRE = digital rectal examination; PSA = prostate specific antigen
* significant differences at 95% CI

Figure C8. Percentage of responses by urologists and primary care physicians to the question "Which test do you believe is the single best screening tool? Do you screen for prostate cancer patients older than 79 years? Do you screen young asymptomatic patients?" (McKnight, 1996)¹⁴⁰



* significant differences at 95% CI

Figure C9. Percentage of responses by urologists and radiation oncologists to the question: “Do you recommend that primary care physicians include PSA testing as a part of the routine physician examinations for men who are at average risk of prostate cancer in each age category?” (Fowler, 2000)¹⁴⁸



* significant differences at 95% confidence level

Figure C10. Percentage of responses by urologists and primary care physicians to the question whether radical prostatectomy or external beam radiation “probably” or “definitely” offers survival benefit for patients with clinically localized prostate cancer (Fowler, 1998)¹⁴¹

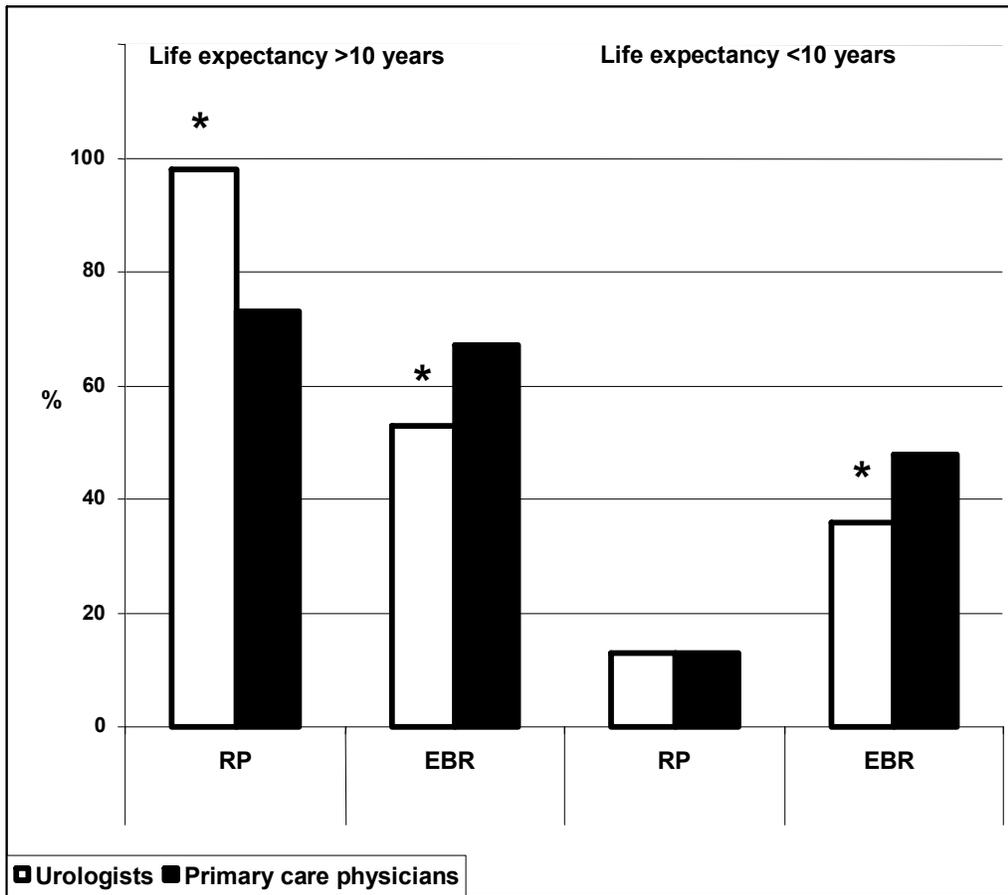
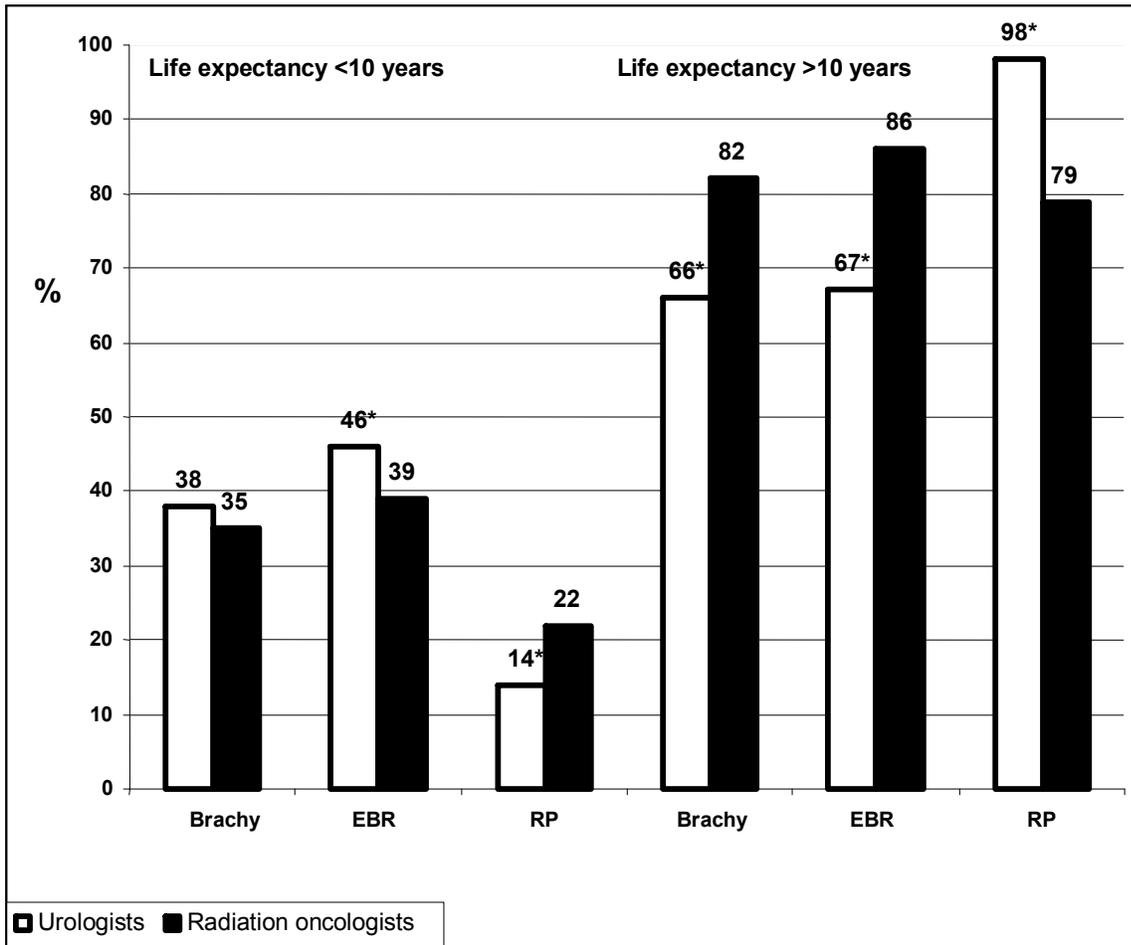


Figure C11. Which therapy offers the best survival to patients with clinically localized prostate cancer? Treatment recommendations by urologists and radiation oncologists (Fowler, 2000)¹⁴⁸



* significant differences at 95% confidence level

Figure C12. Percentage of responses by urologists and radiation oncologists to the question whether they believed that three main potentially curative prostate cancer therapies are overused or underused in the United States (Fowler, 2000)¹⁴⁸

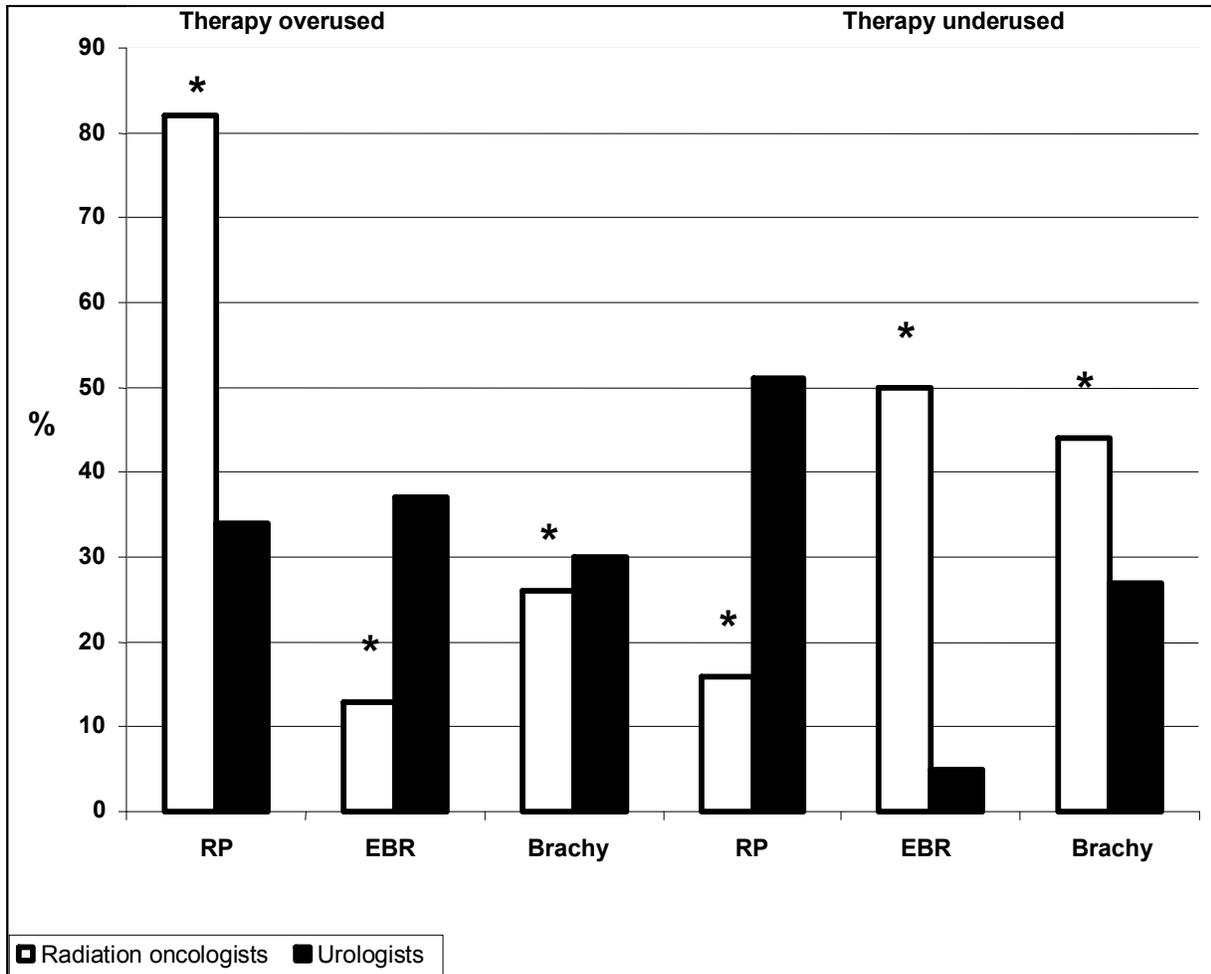


Table C44. Variability in management of prostate cancer (compared with recommended guidelines)

Reference/ Design	Data Source Population	Analysis Risk Adjustment	Management Options	Frequency of Practice	P Values
Hanna, 2002 ¹⁴⁵ Survey	Oncology departments treated urological malignancy	Not reported	Treatment of localized RP	Local PC, patient age 55 52%	
	169 clinical oncologists		External beam radiotherapy	19%	
				Brachy therapy Hormone therapy Medical Surgical Surveillance only Surveillance + hormone	7% 0% 0% 5% 0%
				Bladder outlet obstruction	
			RP	15%	
			External beam radiotherapy	68%	
				Poorly differentiated local tumor	
			RP	9%	
			External beam radiotherapy	77%	
			Brachytherapy	1	
			Hormone therapy medical	3	
McNaughton Collins, 2002 ¹⁴⁷	The American Medical Association Master List of Physicians	Chi-square test		PSA screening for men 75-79 years	
Survey	A random sample of radiation oncologists (559) and urologists (504) working in clinical practice for at least 20 hours weekly	Not reported	Radiation oncologists Urologists	92% 68-81%	<0.01
			Radiation oncologists Brachytherapy for 20% of patients last year	Northeast 35%	Midwest 28% <0.01
			Brachytherapy offers a survival benefit for patients with >10 year life expectancy	87%	2% 0.6
		Brachytherapy has survival value for patients with <10 year life expectancy	29%	28% 0.05	

Table C44. Variability in management of prostate cancer (compared with recommended guidelines) (continued)

Reference/ Design	Data Source Population	Analysis Risk Adjustment	Management Options	Frequency of Practice	P Values	
			Urologists			
			Brachytherapy for 20% of patients last year	40%	17%	<0.01
			Brachytherapy offers a survival benefit for patients with >10 year life expectancy	71%	0%	0.4
			Brachytherapy has survival value for patients with <10 year life expectancy	40%	36%	<0.01
				West	South	
			Brachytherapy for 20% of patients last year	28%	26%	
			Brachytherapy offers a survival benefit for patients with >10 year life expectancy	0%	79%	
			Brachytherapy has survival value for patients with <10 year life expectancy	38%	35%	
			Urologists			
			Brachytherapy for 20% of patients last year	24%	28%	
			Brachytherapy offers a survival benefit for patients with >10 year life expectancy	63%	69%	
			Brachytherapy has survival value for patients with <10 year life expectancy	23%	43%	

Table C44. Variability in management of prostate cancer (compared with recommended guidelines) (continued)

Reference/ Design	Data Source Population	Analysis Risk Adjustment	Management Options	Frequency of Practice	P Values	
Plawker, 1997 ¹⁴³	The American Urological Association (AUA) data	Chi-square	Ultrasound use for all biopsy	95.8%		
Survey	1,500 randomly selected urologists	Not reported	Sextant biopsy	79.5%		
			Biopsy of transition zone	46.7%		
			Use of age specific PSA in patients with normal exams	69.7%		
			Use PSA density when PSA >4 ngg/dL/dl	40.3%		
			Radiological staging	CT	MRI	Bone scan
			All patients regardless of PSA	28.6	3.5	52.4
			PSA >10 ng/dL	12.6	1.7	29.5
			PSA >20 ng/dL	12.4	4.2	11.9
			PSA >30 ng/dL	4.9	0.9	0.3
			PSA >50 ng/dL	2.5	1.3	0.2
Gee, 1995 ¹⁴⁴	The American Urological Association data	Not reported	Radiological staging In patients >70 years with PC and PSA <10 ng/dL			
Survey	A random sample of 514 urologists who had completed a urological residency, practiced urology at least 20 hours a week in 1994, and practiced urology in 1993		Bone scan	72%		
			CT	40%		
			Cystoscopy	33%		
			IVP	25%		
			Laparoscopic lymph node dissection	6%		
			Pelvic MRI	5%		
			Rectal coil MRI	4%		
				Treatment of PC in patients <70 years		
			Radical prostatectomy	95%		
			External beam radiation	36%		
			Observation	10%		
			Hormone therapy	7%		
			Brachytherapy	5%		
			Cryosurgery	2%		
				Treatment of PC in patients >70 years		
			Radical prostatectomy	48%		
			External beam radiation	74%		
			Observation	38%		
			Hormone therapy	17%		
			Brachy therapy	10%		
			Cryosurgery	4%		

Table C44. Variability in management of prostate cancer (compared with recommended guidelines) (continued)

Reference/ Design	Data Source Population	Analysis Risk Adjustment	Management Options	Frequency of Practice	P Values
Shahinian, 2006 ¹⁵⁷ Retrospective cohort	61,717 men with incident prostate cancer (1/1992-12/1999) identified in the SEER-Medicare database. 1,802 urologists providing care within 1 year of cancer diagnosis identified by the Unique Physician Identifier numbers on Medicare physician claims. Rate of ADT in evidence-based group: Mean – 71.3% 4.6% of urologists >71.3% 11.8% of urologists <71.3% Rate of ADT in uncertain-benefit group: Mean – 36.% 15.2% of urologists >36% 8.4% of urologists <36%	Chi-square statistics and logistic regression models adjusted for patient age, comorbidity, ethnicity, socioeconomic status, SEER region, and year of diagnosis and tumor stage and grade.	The evidence-based group: radiation therapy for T3 tumors (regardless of grade) or T2 tumors with high-grade histology (Gleason score of 8–10)	25.38	
			All patients		
			1992-1999	16	
			1992-1996	15.6	
			1997-1999	22.56	
				% of variance in the use of ADT attributable to stage and grade: 6.63	
			Evidence-based group	5.34	
			Uncertain benefit group		
			All patients	13.06	
1992-1999	15.4				
1992-1996	9.71				
1997-1999	To patient characteristics 7.27				
Evidence-based group					
Uncertain benefit group	4.99				
All patients					
1992-1999	8.99				
1992-1996	6.58				
1997-1999	4.29				

Table C45. Association between provider characteristics and patient outcomes

Reference/ Design	Data Source Population	Analysis Risk Adjustment	Outcomes	Provider Characteristics		P Values
Kramolowsky, 1995 ¹⁵⁰ Nonrandomized intervention: physician education on factors that may decrease charges	14 board certified urologists 34 to 62 years old performed 256 consecutive radical retropubic prostatectomies at a 401-bed, community, not for profit hospital	Student's t test and chi- square test	Total charge	Time 1 (baseline) \$17134 ± 653	Time 2 (after intervention) \$13,826 ± 260	<0.01
			Length of stay (days)	7.8 ± 0.3	5.8 ± 0.2	<0.01
		Not reported	Charges/day	\$2229 ± 54	\$2,622 ± 70	<0.01
			Operation time (minutes)	193 ± 5	154 ± 4	
			Estimated blood loss	1053 ± 67	915 ± 50	
			Units transfused	2.5 ± 0.2	1.7 ± 0.1	
			Central arterial lines	43%	21%	
			ICU used	51%	19%	
Epidural used	68%	91%				
Kramolowsky, 1995 ¹⁴⁹ Nonrandomized intervention: physician education on factors that may decrease charges	625 males diagnosed with carcinoma of the prostate gland undergoing radical prostatectomy by one of 20 urologists at 5 community hospitals in VA 1991-1993	Student's t test and chi- square test	Total charge	Time 1 (baseline) \$17,201 ± 943	Time 2 (after intervention) \$15,931 ± 420	<0.01
			Length of stay (days)	\$16,798 ± 683	\$15,286 ± 506	<0.01
		Not reported	Charges/day	\$18,601 ± 694	\$14,084 ± 621	<0.01
				7.7 ± 0.2	5.6 ± 0.1	
Maliski, 2004 ¹⁵⁶ Survey	286 California patients with biopsy-proven prostate cancer, uninsured, with household income less than 200% of the Federal Poverty Level. 233 (81%) consented and completed the	Multivariate logistic regression	Patient outcomes: SF-12	High self-efficacy	Low self efficacy	
			Physical function	64.7 ± 32.9	53.8 ± 35.8	0.03
			Role-physical	62.4 ± 33.0	57.0 ± 33.1	0.30
			Mental health	47.5 ± 12.6	44.3 ± 13.6	0.12
			Role-emotional	73.3 ± 27.2	63.0 ± 27.8	0.02
		Patient age and treatment	Social function	72.7 ± 31.7	52.9 ± 35.2	<0.01
			Vitality	53.1 ± 28.2	45.8 ± 28.1	0.10
			Bodily pain	69.9 ± 30.2	62.0 ± 29.1	0.10
			General health	51.6 ± 29.7	44.6 ± 24.5	0.12
			UCLA PCI			
Scales: Perceived Efficacy in Patient- Physician Interactions (PEPPI) to	Urinary function	74.5 ± 28.0	61.9 ± 32.5	0.01		
	Urinary bother	73.0 ± 34.0	56.6 ± 34.4	<0.01		
	Bowel function	77.4 ± 24.7	65.4 ± 24.2	<0.01		

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Table C45. Association between provider characteristics and patient outcomes (continued)

Reference/ Design	Data Source Population	Analysis Risk Adjustment	Outcomes	Provider Characteristics		P Values
C-119	surveys. All were participants in the Improving Access, Counseling, and Treatment for Californians with Prostate Cancer (IMPACT), a state-funded program providing free prostate cancer treatment to indigent men	assess a person's confidence in his ability to communicate with his physician; prostate-specific HRQOL; the Medical Outcomes Study five-item Mental Health Index (MHI-5)	Bowel bother	75.4 ± 31.7	63.0 ± 27.3	0.01
			Sexual function	34.5 ± 31.5	23.4 ± 26.8	0.02
			Sexual bother	35.6 ± 38.9	23.0 ± 31.6	0.04
			Symptom distress scale	19.2 ± 6.6	24.7 ± 7.9	<0.01
			Satisfaction with care			
			Satisfaction with healthcare received	1.2 ± 0.7	2.1 ± 1.5	<0.01
			Some things could have been better	3.1 ± 2.1	3.6 ± 1.9	0.10
			Have not had as much contact as should have	3.3 ± 2.2	3.8 ± 1.8	0.11
			Amount of time adequate	4.2 ± 2.1	3.6 ± 1.9	0.09
			Could have listened more carefully	5.4 ± 1.2	4.6 ± 1.7	<0.01
			Have explained completely	1.2 ± 0.9	1.9 ± 1.4	<0.01
Have treated me with respect	4.3 ± 2.2	4.1 ± 1.8	0.41			
Could have been kinder	5.7 ± 0.8	4.1 ± 1.8	<0.01			
Have extraordinary confidence in provider	1.6 ± 1.2	2.7 ± 1.6	<0.00			
Diamond, 1991 ¹⁵¹	The Patterns of Care Study (PCS) of all facilities in the U.S. where 770 males were treated for PC in 1978	Logistic regression	In hospital mortality	Facility structure per physician	Annual number of new patients per physician	
Facility survey		Not reported	Major complication	Not significant	Positive	<0.01
			Local Recurrence	Positive	Not significant	<0.01
			Any recurrence	Not significant	Not significant	
Maliski, 2005 ¹⁵⁵	149 males with a biopsy positive for prostate cancer in a large tertiary medical center, an urban Veterans Affairs medical center, and an urban public hospital. Subjects were followed for 6 and 12 months to complete the UCLA Prostate	Multivariate logistic regression	Patient fatigue	Facility	Private	
Secondary analysis of prospective cohort the utilities study		Patient age and treatment	Fatigued	Public	32.14%	
			Not fatigued	67.83%	64.71%	<0.01
			Progression of fatigue	53.49%	46.51%	0.06
Survey			Progression >10 points in fatigue from baseline	Odds ratio	1 (reference)	<0.01
				5.82 (1.78-19.07)		

Table C45. Association between provider characteristics and patient outcomes (continued)

Reference/ Design	Data Source Population	Analysis Risk Adjustment	Outcomes	Provider Characteristics			P Values
	Cancer Index (PCI) questionnaire to measure prostate-specific HRQOL						
Greenwald, 1992 ¹⁵⁸	264 males diagnosed with PC from 1980-1982, identified in the Cancer Surveillance System (CSS), a part of the SEER Program	Cox regression	Sample 1 Treatment received Surgery Radiation Mortality	HMO members vs. fee for service Relative risk 95% CI			
Prospective cohort with two overlapping samples	1,000 consecutive cases of newly diagnosed prostatic cancer from the CSS	Patient age, income, education, treatment, cancer stage, HMO membership	Sample 2 Treatment received Surgery Radiation Mortality	0.26	0.11	0.58	
				2.99	1.26	7.09	
				0.334	0.196	0.734	
				0.45	0.28	0.71	
				4.08	2.49	6.69	
				0.736	0.547	0.991	
Potosky, 1999 ¹⁵⁹	21,741 men age 65 and over diagnosed with prostate cancer between 1985 and the end of 1992 and followed through 1994 in 5 county San Francisco-Oakland metropolitan area, and 13-county Seattle-Puget Sound area	Logistic regression to estimate the odds ratios of receiving one of two treatments for men with nonmetastatic prostate cancer (local and regional stage)	Treatment received Prostatectomy Radiation Conservative management	California HMO 13.6% 28.3% 53.7% 25.2% 31.3% 41.3%			<0.01
Prospective cohort		Patient age, race, education level, and clinical	Prostatectomy Radiation Conservative management	Seattle HMO 17.3% 36.3% 53.3% 31.3% 27% 29.3%			<0.01
			All cause mortality PC mortality	Relative risk HMO vs. Medicare 1.01 (0.94-1.08) 1.25 (1.13-1.39)			

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Table C45. Association between provider characteristics and patient outcomes (continued)

Reference/ Design	Data Source Population	Analysis Risk Adjustment	Outcomes	Provider Characteristics	P Values
	participating in SEER Program	characteristics. The Cox proportional hazards regression model was used to estimate the relative risk of overall and cause-specific 10-year mortality among HMO cases relative to those in the Medicare FFS setting. Patient age at diagnosis, race, stage, grade, comorbidity, and group educational status			

Table C46. Association between physician characteristics and learning curves for treatment of prostate cancer

Reference Procedure	Physician Experience, Training	Cases/ Curves	Operative Time (hours)	% Open Surgery	% Complications	Blood Loss (ml)	% Transfusions	LOS (days)	% Positive Margins	Catheterization (Days)	% Continence	% Potency
Ahlering, 2003 ¹⁶⁰	1 fellowship trained urological oncologist; 1-day da Vinci LRP course + 2 cadaveric robotic LRP	45/12	3.45	0	13.3	145	2.2	1.6	35.5	2.2% in 1 week	1 week-33% pad free	Not reported
Robot assisted LRP (June 2002-March 2003)												
Arai, 2003 ¹⁶¹	6 centers	148	6.7	10.8	37.2	856	6	Not reported	Not reported	Removed in 1 week in 49.3% of cases	Not reported	Not reported
LRP (December 1999 and September 2001)	Several surgeons with no previous experience on LRP											
Baumert, 2004 ¹⁶²	1 surgeon 30 laparoscopic procedures, assisting in 20 LRP	50 50 Total 100/50	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	62.5* 11.1* 12.8-T2 31.8-T3	Not reported	Not reported	Not reported
LRP (December 2000-April 2002)												
Cathelineau, 2004 ⁴⁰	1 surgeon with >400 Transperitoneal LRP	200 A. 100 B. 100	2.8 2.7		10 9	360 375	4 3	5.8 6.1	15 21			
A. Transperitoneal and B. extraperitoneal LRP (2002)	1 surgeon with >80 Transperitoneal LRP											
Dahl, 2003 ¹⁶³	No previous experience	70 1-10 11-70	4.6 6.4 4.6		20	449 811 295			11.4		At 3 months, 85% used 0-1 pad/day	
LRP (May 2000 to May 2001)				1.4			5.7	2.5				

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Table C46. Association between physician characteristics and learning curves for treatment of prostate cancer (continued)

Reference Procedure	Physician Experience, Training	Cases/ Curves	Operative Time (hours)	% Open Surgery	% Complications	Blood Loss (ml)	% Transfusions	LOS (days)	% Positive Margins	Catheterization (Days)	% Continence	% Potency	
Eden, 2004 ¹⁶⁴	1 surgeon, unknown experience	200								Days	Pad free (3m)	Erection (3m)	
Transperitoneal laparoscopic radical prostatectomy (TLRP) and extraperitoneal approach (ELRP)		TLRP	4.0*	0.5	4	310	1	3.8*	16	11.3	60	10	
		ELRP	3.2*	0	2	201.5	0	2.6*	16	10.1	70	60	
		1-100											
		TLRP		0	2	320	0	3.5	14	10			
		ELRP		0		246.2	0	2.5	10	10			
		150-200											
		TLRP	3.6								56	20	
		ELRP	3.1								80	70	
El-Feel, 2003 ^{165,166}	A. 2 surgeons (>100 cases) B. 2 junior surgeons (<30 cases)	100											
LRP (November 2001 to May 2002)		randomly assigned among 4 surgeons											
		LRP	3.6										
		LRP with robot	4.9										
		A. LRP	3										
		A. LRP	4.9										
		LRP/robot											
		B. LRP	4.8										
		LRP+ nerve sparing											
		A.	3*										
		B.	4.1*										
		LRP+ pelvic lymphadenectomy											
		A.	3.7*										
		B.	5.4*										
		LRP+ sural nerve grafting											
A.	4.6*												
B.	7.7*												

Table C46. Association between physician characteristics and learning curves for treatment of prostate cancer (continued)

Reference Procedure	Physician Experience, Training	Cases/ Curves	Operative Time (hours)	% Open Surgery	% Complications	Blood Loss (ml)	% Transfusions	LOS (days)	% Positive Margins	Catheterization (Days)	% Continence	% Potency
El-Feel, 2003 ¹⁶⁵ (November 2001 to May 2002)	A. 2 surgeons (>100 cases) B. 2 junior surgeons (<30 cases)	100 randomly assigned among 4 surgeons A. B.	3.6* 5.8*						19* 34* Adjusted OR 2 (Not significant)			
Fabrizio, 2003 ¹⁶⁷ Transperitoneal LPR (March 2001 - September 2001)	A. 12 cases - the mentor (>200 LRP) with assisting trainee B. 18 cases - the trainee with assisting mentor C. 30 cases – the trainee alone with assisting urological residents	30 A. B. C.	4.1 4.3 5.2			150 250 250	5.6	3 3 3	16 22 39	13 11 9		
Freder, 2005 ¹⁶⁸ LPR	A. 1 surgeon (600 cases open retropubic RP and laparoscopy) B. 1 surgeon (150 cases open retropubic RP and laparoscopy) C. 1 surgeon (150 cases in laparoscopis). D. fellows in laparoscopic program	1,000 A. 1-50 51-100 101-150 B. 1-50 51-100 101-150 C. 1-50 51-100 101-150 D. 1-50 51-100 101-150	5.5* 5.0* 3.3* 4.8* 3.9* 3.5) 4.5* 3.9* 3.9* 4.1	16 8 12 12 16 4 20 36 0 4 4 0					4.3 0 10.3 0 12.5 8.5 9.3 0 6.3 15.3 NA	<14 days 66* 92* 88* 70* 66* 68* 70* 64* 84* 40*		

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Table C46. Association between physician characteristics and learning curves for treatment of prostate cancer (continued)

Reference Procedure	Physician Experience, Training	Cases/ Curves	Operative Time (hours)	% Open Surgery	% Complications	Blood Loss (ml)	% Transfusions	LOS (days)	% Positive Margins	Catheterization (Days)	% Continence	% Potency	
Ghavamian, 2004 ¹⁶⁹ LPR transperitoneal LRP and extraperitoneal LRP (May 2001- Spetember 2002)	1 surgeon with fellowship in urologic oncology with laparoscopic experience	60											
		1-10	6.9*		80	316							
		11-20	4.7		40	398							
		21-30	4.1		30	252							
		31-40	3.7		30	291							
41-60	3.3		5	277									
Hoznek, 2001 ¹⁷⁰ LPR (May 1998- December 2000)	1 surgeon with unknown experience	134											
		1-10	8.1					9.1					
		11-20	7.8					5.5					
		21-40	5.1					7.3					
		41-60	4.2					4.8					
		61-80	3.9					6.5					
		81-100	4.0					6.8					
101-120	4.8					5.8							
121-134	4.5					5.6							
Keyes, 2006 ¹⁷¹ Prostate brachytherapy (July 1998- Novemebr 2002)	Seven oncologists with >20 procedures experience	805											
		1-200 cases			Acute urinary retention								
		201-400			1								
		401-600			1.2 (0.7-1.9)								
		601-805			0.5 (0.3-0.9)								
					0.3 (0.2-0.7)								
					Prolonged AUR								
1-200 cases			1										
201-400			0.9 (0.4-1.9)										
401-600			0.4 (0.2-1)										
601-805			0.4 (0.1-0.9)										
Rassweiler, 2003 ⁴⁷ LPR vs. radical prostatectomy (March 1999- September 2002)	2 surgeons performed both operations	1-219	4.8	3.7	6.4	1,100	30.1	12		12.8% (7)	9.7		
		220-439	3.6*	0.5	4.1*	800*	9.6*	11		13.2% (7)	8.3		

Table C46. Association between physician characteristics and learning curves for treatment of prostate cancer (continued)

Reference Procedure	Physician Experience, Training	Cases/ Curves	Operative Time (hours)	% Open Surgery	% Complications	Blood Loss (ml)	% Transfusions	LOS (days)	% Positive Margins	Catheterization (Days)	% Continence	% Potency
Stolzenburg, 2005 ¹⁷²	4 trainees in mentor-initiated program	Camera holders/assist										
Endoscopic extraperitoneal radical prostatectomy		4/140		4			4		14	7.6 (4; 20)		
		62/15		0			0		12	None		
		20/45		0			0		15	5.9 (5; 10)		
		5/18		0			0		7	5.4 (5; 7)		
	Mentor			0			0		12	6.2 (4; 14)		

* Significant difference at 95% confidence interval

Table C47. Distribution of urologists and radiation oncologists in the United States*

	Total Number of Urologists		Total Number of Radiation Oncologists	
	Mean	Standard Error	Mean	Standard Error
East North	465	39	207	16
East South	207	50	68	20
Middle Atlantic	878	48	336	19
Mountain	295	31	118	12
New England	351	34	177	14
Pacific	460	39	199	16
South Atlantic	492	31	177	12
West North	154	35	64	14
West South	396	43	139	17
Midwest	298	28	3,903	39
Northeast	534	30	233	12
South	418	24	148	10
West	364	26	151	10
USA	10,026	102	3,903	41

* An average of absolute number of physicians identified themselves as urologists in the U.S. were obtained from the surveys conducted by the American Medical Association from 1999-2005¹⁷³⁻¹⁷⁶

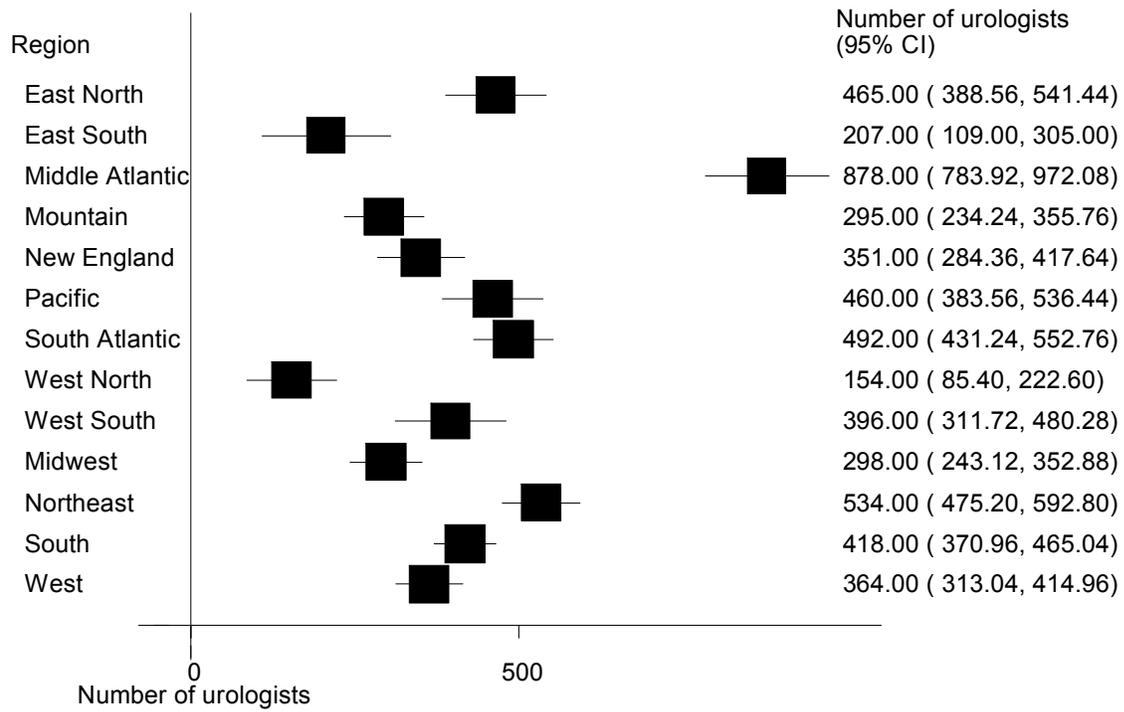
Table C48. Significant geographic differences in total numbers of urologists

Regions		Mean Differences in Total Number	Standard Error	p
East North	East South	258	64	<0.01
East North	Middle Atlantic	-414	62	<0.01
East North	Mountain	169	50	<0.01
East North	New England	114	52	0.03
East North	West North	311	52	<0.01
East South	Middle Atlantic	-671	70	<0.01
East South	New England	-144	61	0.02
East South	Pacific	-253	64	<0.01
East South	South Atlantic	-285	59	<0.01
East South	West South	-189	66	<0.01
Middle Atlantic	Mountain	583	57	<0.01
Middle Atlantic	New England	527	59	<0.01
Middle Atlantic	Pacific	418	62	<0.01
Middle Atlantic	South Atlantic	387	57	<0.01
Middle Atlantic	West North	725	60	<0.01
Middle Atlantic	West South	482	64	<0.01
Mountain	Pacific	-165	50	<0.01
Mountain	South Atlantic	-196	44	<0.01
Mountain	West North	142	47	<0.01
New England	Pacific	-109	52	0.04
New England	South Atlantic	-141	46	<0.01
New England	West North	197	49	<0.01
Pacific	West North	306	52	<0.01
South Atlantic	West North	338	47	<0.01
West North	West South	-242	55	<0.01
Midwest-Northeast	Northeast	-236	41	<0.01
Midwest-South	South	-120	37	<0.01
Northeast-South	South	116	38	<0.01
Northeast-West	West	169	39	<0.01

Table C49. Significant geographic differences in total numbers of radiation oncologists

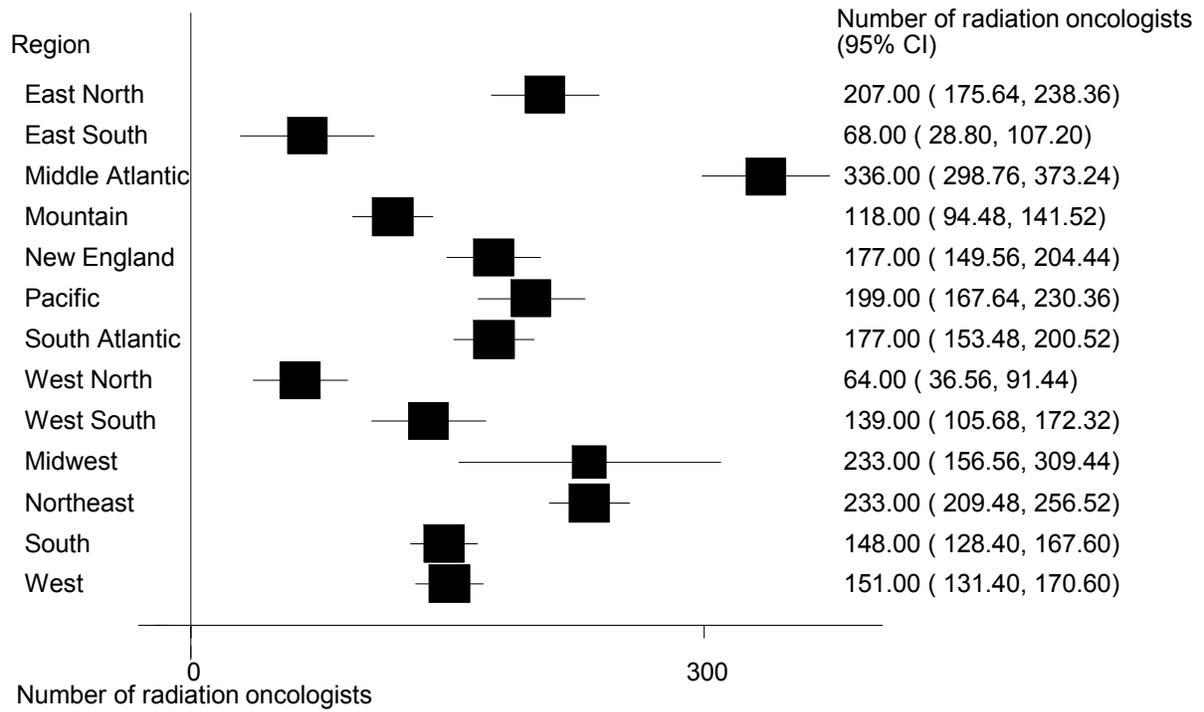
Regions	Mean Differences in Total Number	Standard Error	p
East North - East South	139	25	<0.01
East North - Middle Atlantic	-129	25	<0.01
East North - Mountain	89	20	<0.01
East North - West North	143	21	<0.01
East North - West South	68	23	<0.01
East South - Middle Atlantic	-268	28	<0.01
East South - Mountain	-50	24	0.04
East South - New England	-109	24	<0.01
East South - Pacific	-130	25	<0.01
East South - South Atlantic	-108	24	<0.01
East South - West South	-71	26	0.01
Middle Atlantic - Mountain	218	23	<0.01
Middle Atlantic - New England	159	24	<0.01
Middle Atlantic - Pacific	137	25	<0.01
Middle Atlantic - South Atlantic	160	23	<0.01
Middle Atlantic - West North	272	24	<0.01
Middle Atlantic - West South	197	26	<0.01
Mountain - New England	-59	18	<0.01
Mountain - Pacific	-81	20	<0.01
Mountain - South Atlantic	-59	18	<0.01
Mountain - West North	54	19	<0.01
New England - West North	113	20	<0.01
Pacific - West North	134	21	<0.01
Pacific - West South	60	23	0.01
South Atlantic - West North	112	19	<0.01
West North - West South	-75	22	<0.01
Midwest - Northeast	-103	16	<0.01
Northeast - South	85	15	<0.01
Northeast - West	81	16	<0.01

Figure C13. Distribution of urologists* in the U.S. regions (pooled analysis from 1999-2004)



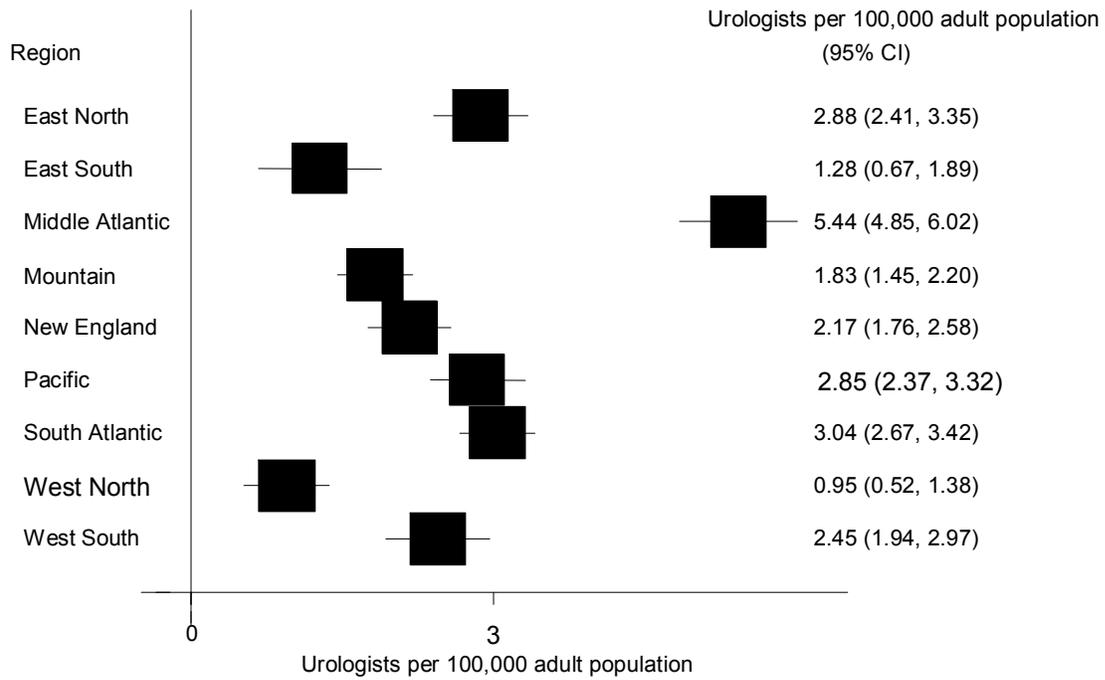
* An average of absolute number of physicians identified themselves as urologists in the U.S. were obtained from the surveys conducted by the American Medical Association from 1999-2005¹⁷³⁻¹⁷⁷

Figure C14. Distribution of radiation oncologists* in U.S. regions



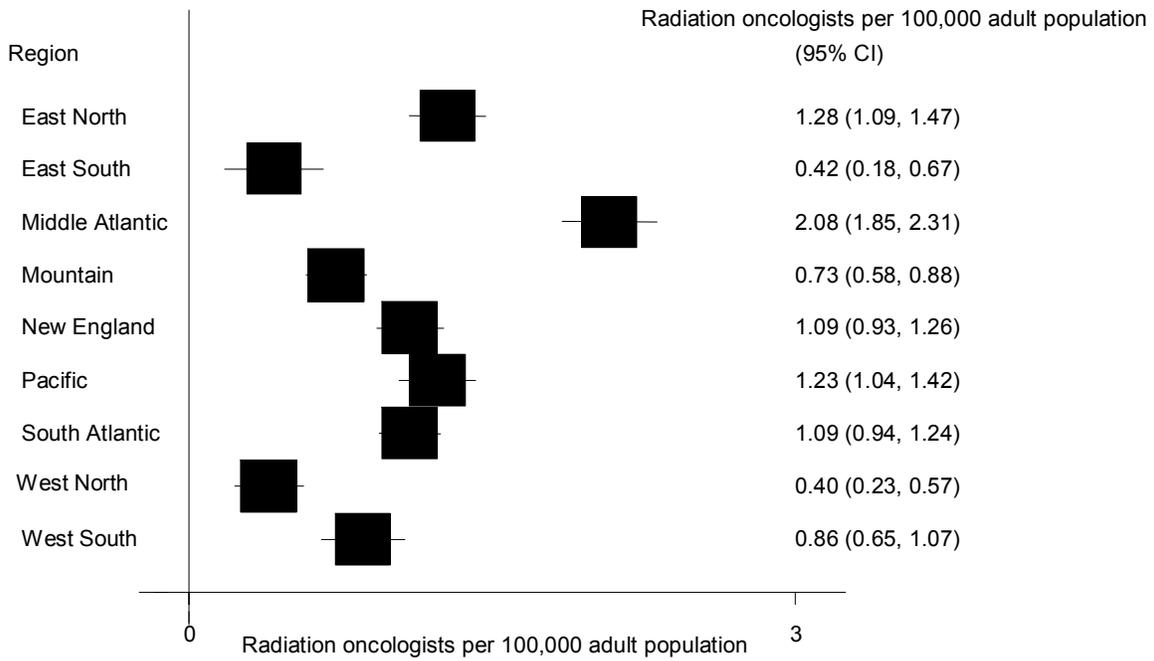
* An average of absolute number of physicians identified themselves as radiation oncologists in the U.S. were obtained from the surveys conducted by the American Medical Association from 1999-2005. ¹⁷³⁻¹⁷⁷

Figure C15. Ratio* of urologists (1999-2004) per 100,000 adult population (2002) in U.S. regions



* The ratio was calculated with an average of number of urologists in each state from 1999-2004 in numerator and the Census 2002 adult population in each state in denominator.

Figure C16. Ratio* of radiation oncologists (1999-2004) per 100,000 adult population (2002) in U.S. regions



* The ratio was calculated with an average number of radiation oncologists in each state from 1999-2004 in numerator and the Census 2002 adult population in each state in denominator.

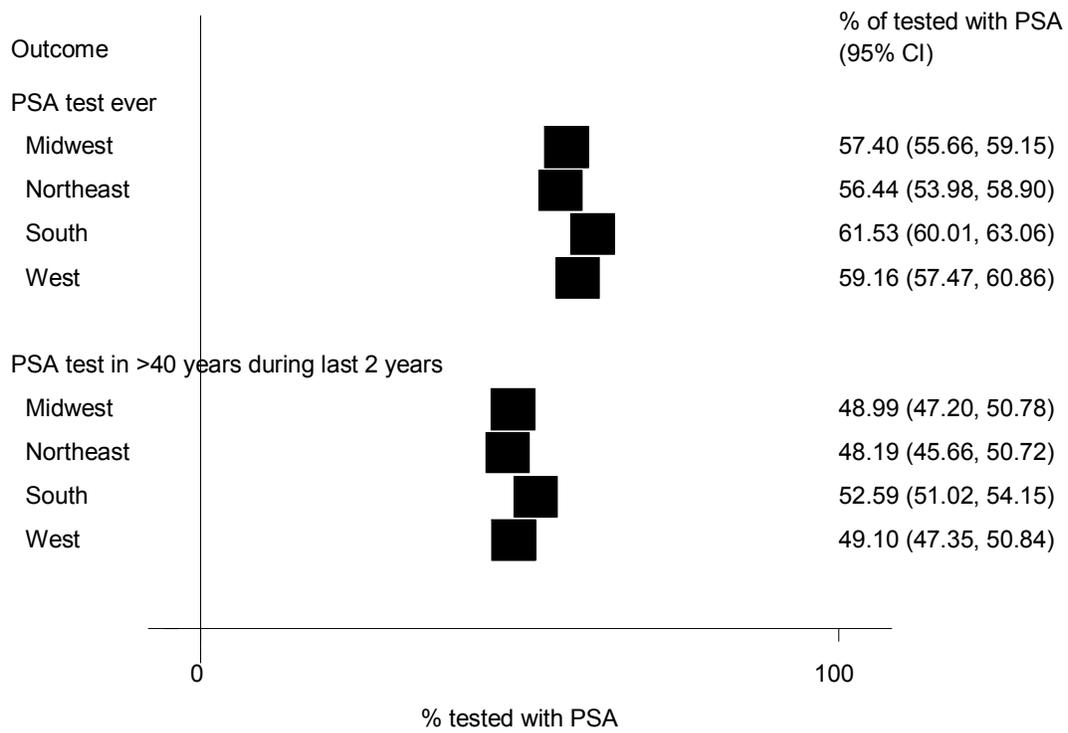
Table C50. Significant geographic differences in % of males >40 years of age who had PSA test during last 2 years

Regions		Differences in % of PSA Testing			P Value
		Mean %	Lower 95% CI	Upper 95% CI	
East North	Pacific	4.07	0.49	7.65	0.03
East North	South Atlantic	-5.77	-9.02	-2.52	<0.01
East South	Pacific	6.16	2.40	9.92	<0.01
East South	South Atlantic	-3.67	-7.12	-0.23	0.04
Mountain	New England	3.57	0.36	6.79	0.03
Mountain	Pacific	6.14	2.77	9.50	<0.01
Mountain	South Atlantic	-3.70	-6.71	-0.69	0.02
New England	South Atlantic	-7.27	-10.72	-3.83	<0.01
Pacific	South Atlantic	-9.84	-13.42	-6.26	<0.01
Pacific	West North	-3.90	-7.48	-0.33	0.03
Pacific	West South	-6.18	-9.94	-2.42	<0.01
South Atlantic	West North	5.93	2.69	9.18	<0.01
South Atlantic	West South	3.66	0.21	7.10	0.04
Midwest	South	-3.60	-5.97	-1.22	<0.01
Northeast	South	-4.39	-7.37	-1.42	<0.01
South	West	3.49	1.14	5.84	<0.01

Table C51. Significant geographic differences in % of males who ever had PSA test

Regions		Differences in % of PSA Testing			P Value
		Mean %	Lower 95% CI	Upper 95% CI	
East North	Mountain	-3.49	-6.37	-0.62	0.02
East North	South Atlantic	-5.65	-8.76	-2.55	<0.01
East North	West South	-3.58	-6.88	-0.29	0.03
East South	New England	4.26	0.78	7.73	0.02
East South	Pacific	4.41	0.81	8.00	0.02
East South	South Atlantic	-3.79	-7.09	-0.50	0.02
Middle Atlantic	New England	5.77	0.28	11.26	0.04
Middle Atlantic	Pacific	5.92	0.36	11.49	0.04
Mountain	New England	5.89	2.81	8.97	<0.01
Mountain	Pacific	6.04	2.83	9.26	<0.01
Mountain	West North	4.05	1.18	6.93	0.01
New England	South Atlantic	-8.05	-11.35	-4.76	<0.01
New England	West South	-5.98	-9.45	-2.51	<0.01
Pacific	South Atlantic	-8.20	-11.63	-4.78	<0.01
Pacific	West South	-6.13	-9.73	-2.54	<0.01
South Atlantic	West North	6.21	3.11	9.32	<0.01
West North	West South	-4.14	-7.44	-0.85	0.01
Midwest	South	-4.13	-6.44	-1.81	<0.01

Figure C18. Geographic differences in PSA testing in U.S. regions*



* Average responses in U.S. regions to the BRFSS questionnaire¹³⁸ having PSA test ever and during last 2 years in males older than 40 years

Figure C19. Geographic variations in age adjusted incidence of prostate cancer per 100,000 male population (pooled analysis from 4 studies and CDC data)

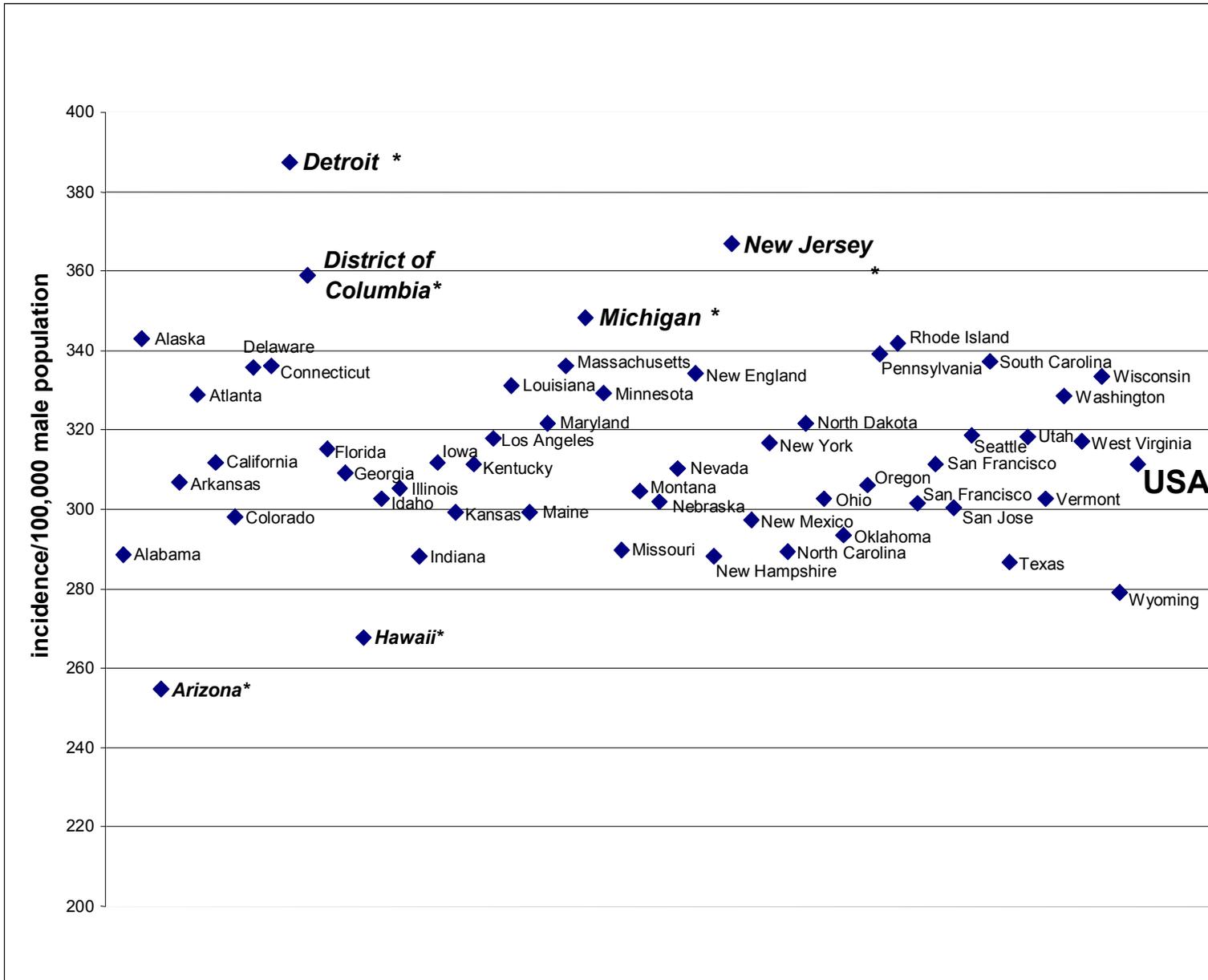


Table C52. Incidence of prostate cancer in the U.S. regions reported in individual studies

Region	Incidence	Lower 95% CI	Upper 95% CI
<i>East North</i>			
Lu-Yao, 1994 ¹⁰²	323.2	192.3	454.0
Jemal, 2005 ¹⁰⁵	487.3	396.1	578.4
CDC, 1999-2004 ¹⁷⁸	183.2	175.4	191.0
<i>East South</i>			
Jemal, 2005 ¹⁰⁵	383.0	225.1	540.8
CDC, 1999-2004 ¹⁷⁸	167.8	150.8	184.9
<i>Middle Atlantic</i>			
Jemal, 2005 ¹⁰⁵	514.5	402.9	626.1
CDC, 1999-2004 ¹⁷⁸	199.4	188.5	210.4
<i>Mountain</i>			
Lu-Yao, 1994 ¹⁰²	334.3	241.8	426.8
Jemal, 2005 ¹⁰⁵	401.5	327.1	475.9
Escobedo, 2004 ¹⁰⁶	118.3	42.8	193.7
CDC, 1999-2004 ¹⁷⁸	161.8	154.0	169.7
<i>New England</i>			
Lu-Yao, 1994 ¹⁰²	251.5	120.6	382.3
Jemal, 2005 ¹⁰⁵	434.6	355.7	513.6
Escobedo, 2004 ¹⁰⁶	158.9	83.4	234.3
CDC, 1999-2004 ¹⁷⁸	192.0	183.7	200.4
<i>Pacific</i>			
Lu-Yao, 1994 ¹⁰²	392.8	317.3	468.3
Jemal, 2005 ¹⁰⁵	447.6	368.7	526.5
CDC, 1999-2004 ¹⁷⁸	177.9	169.8	185.9
<i>South Atlantic</i>			
Lu-Yao, 1994 ¹⁰²	332.0	201.1	462.8
Jemal, 2005 ¹⁰⁵	467.7	397.1	538.2
CDC, 1999-2004 ¹⁷⁸	186.0	178.2	193.7
<i>USA</i>			
Lu-Yao, 1994 ¹⁰²	329.5	198.7	460.3
CDC, 1999-2004 ¹⁷⁸	175.1	153.9	196.4
<i>West North</i>			
Lu-Yao, 1994 ¹⁰²	291.7	160.8	422.5
Jemal, 2005 ¹⁰⁵	444.6	344.8	544.4
Escobedo, 2004 ¹⁰⁶	152.2	76.8	227.6
CDC, 1999-2004 ¹⁷⁸	169.0	160.2	177.7
<i>West South</i>			
Jemal, 2005 ¹⁰⁵	438.1	280.2	595.9
CDC, 1999-2004 ¹⁷⁸	166.9	156.7	177.2

Figure C20. Incidence of prostate cancer (per 100,000 male population) in U.S. regions (CDC data, 1999-2004) (U.S. Cancer Statistics Working Group, 2005)

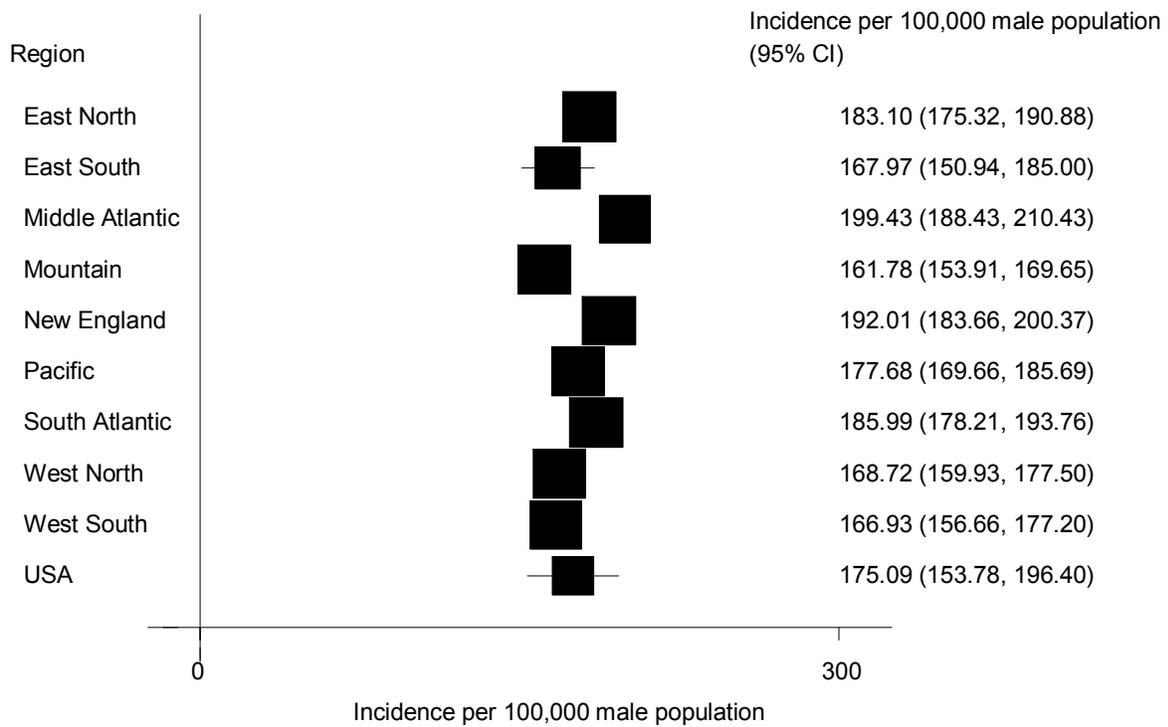


Table C53. Regional variations in age-standardized prostate cancer incidence/100,000 male population (CDC data, 1999-2004) (pair-wise comparisons between U.S. Census regions)

Regions		Difference	Standard Error	P Value
East North	East South	15.13	9.54	0.11
East North	Middle Atlantic	-16.33	6.86	0.02
East North	Mountain	21.32	5.64	0.00
East North	New England	-8.91	5.82	0.13
East North	Pacific	5.42	5.69	0.34
East North	South Atlantic	-2.89	5.60	0.61
East North	West North	14.38	5.98	0.02
East North	West South	16.17	6.56	0.01
East North	USA	8.01	11.56	0.49
East South	Middle Atlantic	-31.46	10.33	0.00
East South	Mountain	6.19	9.56	0.52
East South	New England	-24.04	9.67	0.01
East South	Pacific	-9.71	9.59	0.31
East South	South Atlantic	-18.02	9.54	0.06
East South	West North	-0.75	9.76	0.94
East South	West South	1.04	10.13	0.92
East South	USA	-7.12	13.90	0.61
Middle Atlantic	Mountain	37.65	6.89	<.01
Middle Atlantic	New England	7.42	7.04	0.29
Middle Atlantic	Pacific	21.75	6.93	0.00
Middle Atlantic	South Atlantic	13.44	6.86	0.05
Middle Atlantic	West North	30.71	7.17	<.01
Middle Atlantic	West South	32.50	7.67	<.01
Middle Atlantic	USA	24.34	12.22	0.05
Mountain	New England	-30.23	5.85	<.01
Mountain	Pacific	-15.90	5.72	0.01
Mountain	South Atlantic	-24.21	5.64	<.01
Mountain	West North	-6.94	6.01	0.25
Mountain	West South	-5.15	6.59	0.43
Mountain	USA	-13.31	11.57	0.25
New England	Pacific	14.34	5.90	0.02
New England	South Atlantic	6.02	5.81	0.30
New England	West North	23.30	6.18	0.00
New England	West South	25.08	6.74	0.00
New England	USA	16.92	11.66	0.15
Pacific	South Atlantic	-8.31	5.69	0.14
Pacific	West North	8.96	6.06	0.14
Pacific	West South	10.74	6.64	0.11
Pacific	USA	2.59	11.60	0.82
South Atlantic	West North	17.27	5.98	0.00
South Atlantic	West South	19.06	6.56	0.00
South Atlantic	USA	10.90	11.55	0.35
West North	West South	1.78	6.89	0.80
West North	USA	-6.37	11.74	0.59
West South	USA	-8.16	12.05	0.50

Table C54. Significant geographic differences in incidence of prostate cancer among differences races (CDC data, 1999-2004) (pair-wise comparisons between the US Census regions)

Region		Difference	Standard Error	P Value
African American				
East North	East South	25.93	9.50	0.01
East North	Mountain	52.58	6.65	<.01
East North	West North	42.25	6.49	<.01
East North	West South	31.80	7.09	<.01
East South	Middle Atlantic	-38.44	10.40	0.00
East South	Mountain	26.66	9.92	0.01
East South	New England	-20.86	10.05	0.04
East South	Pacific	-24.19	9.76	0.01
East South	Atlantic tic	-29.25	9.41	0.00
Middle Atlantic	Mountain	65.09	7.89	<.01
Middle Atlantic	New England	17.57	8.06	0.03
Middle Atlantic	West North	54.76	7.75	<0.01
Middle Atlantic	West South	44.31	8.26	<0.01
Mountain	New England	-47.52	7.42	<0.01
Mountain	Pacific	-50.85	7.02	<0.01
Mountain	Atlantic tic	-55.90	6.53	<0.01
Mountain	West South	-20.78	7.64	0.01
Mountain	USA	-43.42	13.06	0.00
New England	West North	37.19	7.27	<0.01
New England	West South	26.74	7.81	0.00
Pacific	West North	40.51	6.87	<0.01
Pacific	West South	30.06	7.43	<0.01
South Atlantic	West North	45.57	6.37	<0.01
South Atlantic	West South	35.12	6.97	<0.01
West North	USA	-33.09	12.97	0.01
Hispanic				
East North	Middle Atlantic	-41.19	8.49	<0.01
East North	New England	-61.49	7.27	<0.01
East South	New England	-56.60	24.43	0.02
Middle Atlantic	Mountain	37.78	8.33	<0.01
Middle Atlantic	New England	-20.30	8.77	0.02
Middle Atlantic	Pacific	37.81	8.49	<0.01
Middle Atlantic	South Atlantic	55.78	9.30	<0.01
Middle Atlantic	West North	47.96	9.17	<0.01
Middle Atlantic	West South	28.93	9.31	0.00
Middle Atlantic	USA	36.08	13.87	0.01
Mountain	New England	-58.08	7.08	<0.01
Mountain	South Atlantic	18.00	7.73	0.02
New England	Pacific	58.11	7.27	0.01
New England	South Atlantic	76.08	8.20	<0.01
New England	West North	68.25	8.05	<0.01
New England	West South	49.23	8.21	<0.01
New England	USA	56.38	13.16	<0.01
Pacific	South Atlantic	17.97	7.90	0.02
South Atlantic	West South	-26.85	8.77	0.00
West North	West South	-19.03	8.63	0.03
Whites				
East North	East South	27.68	9.50	0.00
East North	West South	16.42	7.09	0.02
East South	Middle Atlantic	-37.33	10.40	0.00
East South	Mountain	-25.03	9.44	0.01
East South	New England	-38.43	9.50	<0.01
East South	Pacific	-31.19	9.50	0.00
East South	South Atlantic	-21.13	9.41	0.03
East South	West North	-27.00	9.67	0.01
Middle Atlantic	South Atlantic	16.20	7.25	0.03
Middle Atlantic	West South	26.07	8.26	0.00

Table C54. Significant geographic differences in incidence of prostate cancer among differences races (CDC data, 1999-2004) (continued)

Region		Difference	Standard Error	P Value
Mountain	New England	-13.40	5.91	0.02
Mountain	West South	13.77	7.01	0.05
New England	South Atlantic	17.30	5.88	0.00
New England	West South	27.17	7.09	0.00
Pacific	West South	19.92	7.09	0.01
West North	West South	15.74	7.32	0.03

Table C55. Incidence of localized prostate cancer reported in individual studies

Region	Incidence	Lower 95% CI	Upper 95% CI
East North Jemal, 2005 ¹⁰⁵	396.2	325.7	466.7
East South Jemal, 2005 ¹⁰⁵	268.7	146.6	390.8
Middle Atlantic Jemal, 2005 ¹⁰⁵	401.2	314.8	487.5
Mountain Jemal, 2005 ¹⁰⁵	312.5	254.9	370.0
Escobedo, 2004 ¹⁰⁶	92.7	19.3	166.0
New England Jemal, 2005 ¹⁰⁵	354.2	293.2	415.3
Escobedo, 2004 ¹⁰⁶	110.6	37.2	183.9
Pacific Jemal, 2005 ¹⁰⁵	348.3	287.3	409.4
South Atlantic Jemal, 2005 ¹⁰⁵	367.5	312.9	422.0
West North Jemal, 2005 ¹⁰⁵	367.6	290.4	444.8
Escobedo, 2004 ¹⁰⁶	103.7	30.4	177.0

Table C56. Correlation between incidence, mortality, and physicians' distribution in geographic regions (state level)

Race	Outcome		Number of Urologists	Number of Radiation Oncologists
Whites	Incidence	Correlation coefficient	-0.04	-0.03
		p value	0.57	0.66
	Mortality	Correlation coefficient	-0.16	-0.15
		p value	0.01	0.02
Blacks	Incidence	Correlation coefficient	0.08	0.09
		p value	0.26	0.20
	Mortality	Correlation coefficient	-0.04	-0.06
		p value	0.63	0.44
Combined	Incidence	Correlation coefficient	-0.02	-0.02
		p value	0.74	0.82
	Mortality	Correlation coefficient	-0.07	-0.09
		p value	0.23	0.17
	PSA testing	Correlation coefficient	0.14	0.09
		p value	0.16	0.36

Table C57. Correlation between incidence and mortality in different races in geographic regions (state level) (CDC data)

Race	Outcome	Mortality
Whites	Incidence	Correlation coefficient
		0.5
Blacks	Incidence	p value
		0.0002
		Correlation coefficient
		-0.14
		p value
		0.41

Table C58. Correlation between incidence, mortality, and screening in geographic regions (state level) (CDC data)

		Incidence	Mortality	PSA Test Last 2 Years	PSA Test Ever
Incidence	Correlation coefficient	1			
	p value				
Mortality	Correlation coefficient	0.2	1		
	p value	0.13			
PSA test last 2 years	Correlation coefficient	0.27	0.43	1	
	p value	0.06	0.0018		
PSA test ever	Correlation coefficient	0.18	0.44	0.94	1
	p value	0.23	0.0012	<0.01	

Table C59. Proportion of patients treated with external beam therapy, brachytherapy, primary androgen deprivation therapy, radiation, and watchful waiting (%) pooled analysis

	External Beam Therapy	Brachytherapy	Primary Androgen Deprivation Therapy	Radiation Therapy	Watchful Waiting
Midwest	25.92	10.02	15.70	27.38	7.24
Northeast	33.72	4.86	17.14	27.72	6.57
South	27.42	10.69	13.39	28.58	5.34
West	22.74	6.36	14.11	28.10	14.00
East North	25.97	9.55	17.64	30.69	7.04
East South	24.14	10.83	18.68		5.34
Middle Atlantic	33.72	4.18	8.50		6.22
Mountain	21.54	6.43	11.81	24.51	13.77
New England	33.76	5.11	17.34	26.88	6.69
Pacific	24.21	6.27	15.70	29.09	14.45
South Atlantic	29.85	10.63	13.11	27.74	5.34
West North	25.94	10.58	13.80	22.40	7.38
West South	24.14	10.83	18.68		5.34

Table C60. Correlation between proportion of patients with different primary treatments and total number of urologists and radiation oncologists in geographic regions (state level)

		Radical Prostatectomy	External Beam Radiotherapy	Brachytherapy	Primary Androgen Deprivation	Watchful Waiting
Urologists	Correlation coefficient	-0.57065	0.58002	-0.54	-0.56	-0.10
	p value	0.1086	0.1016	0.13	0.11	0.79
Radiation Oncologists	Correlation coefficient	-0.66288	0.63121	-0.65	-0.50	-0.02
	p value	0.0517	0.0683	0.06	0.17	0.95

Figure C21. Percentage of patients with prostate cancer treated with external beam radiation as an initial therapy in the U.S. regions (pooled analysis)

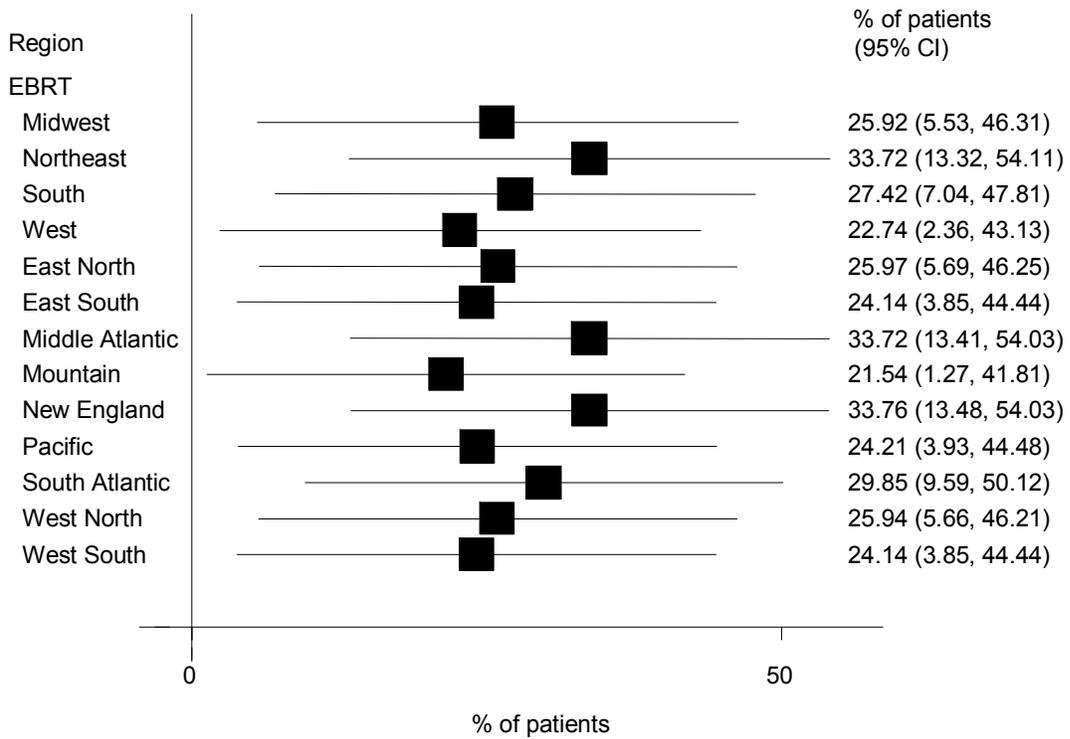


Table C61. Significant variations in proportion of patients treated with external beam therapy

Region		Mean Differences	Lower 95% CI	Upper 95% CI	P Value
East North	East South	1.83	0.06	3.59	0.04
East North	Middle Atlantic	-7.75	-9.68	-5.82	<0.01
East North	Mountain	4.43	2.96	5.90	<0.01
East North	New England	-7.79	-9.30	-6.27	<0.01
East North	Pacific	1.76	0.24	3.29	0.02
East North	South Atlantic	-3.88	-5.27	-2.50	<0.01
East North	West South	1.83	0.06	3.59	0.04
East South	Middle Atlantic	-9.58	-11.67	-7.49	<0.01
East South	Mountain	2.60	0.93	4.28	<0.01
East South	New England	-9.61	-11.33	-7.90	<0.01
East South	South Atlantic	-5.71	-7.31	-4.11	<0.01
East South	West North	-1.79	-3.51	-0.08	0.04
Middle Atlantic	Mountain	12.18	10.33	14.03	<0.01
Middle Atlantic	Pacific	9.52	7.63	11.40	<0.01
Middle Atlantic	South Atlantic	3.87	2.09	5.65	<0.01
Middle Atlantic	West North	7.79	5.90	9.67	<0.01
Middle Atlantic	West South	9.58	7.49	11.67	<0.01
Mountain	New England	-12.22	-13.63	-10.81	<0.01
Mountain	Pacific	-2.67	-4.08	-1.25	<0.01
Mountain	South Atlantic	-8.31	-9.58	-7.05	<0.01
Mountain	West North	-4.40	-5.81	-2.98	<0.01
Mountain	West South	-2.60	-4.28	-0.93	<0.01
New England	Pacific	9.55	8.09	11.01	<0.01
New England	South Atlantic	3.91	2.59	5.22	<0.01
New England	West North	7.82	6.36	9.28	<0.01
New England	West South	9.61	7.90	11.33	<0.01
Pacific	South Atlantic	-5.65	-6.97	-4.32	<0.01
Pacific	West North	-1.73	-3.19	-0.27	0.02
South Atlantic	West North	3.92	2.59	5.24	<0.01
South Atlantic	West South	5.71	4.11	7.31	<0.01
West North	West South	1.79	0.08	3.51	0.04
Midwest	Northeast	-7.79	-9.15	-6.44	<0.01
Midwest	South	-1.50	-2.66	-0.34	0.01
Midwest	West	3.18	1.96	4.40	<0.01
Northeast	South	6.30	5.04	7.56	<0.01
Northeast	West	10.97	9.66	12.29	<0.01
South	West	4.68	3.56	5.79	<0.01

Figure C22. Percentage of patients with prostate cancer treated with radiation as an initial therapy in U.S. regions (pooled analysis)

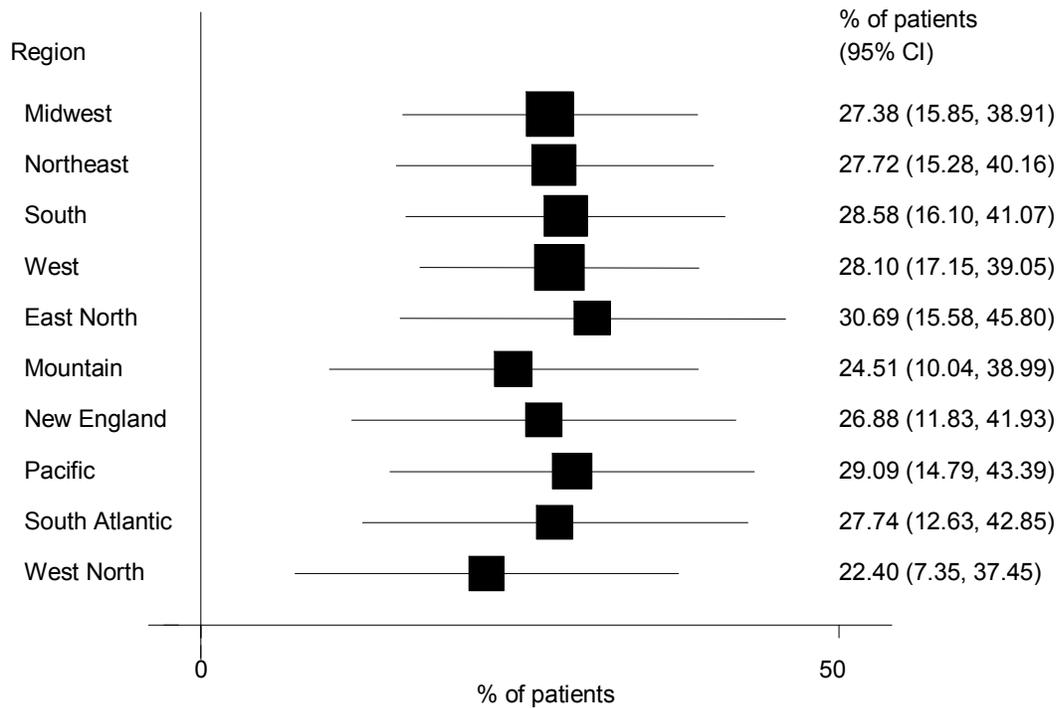


Figure C23. Percentage of patients with localized prostate cancer treated with watchful waiting as an initial therapy in U.S. regions (pooled analysis)

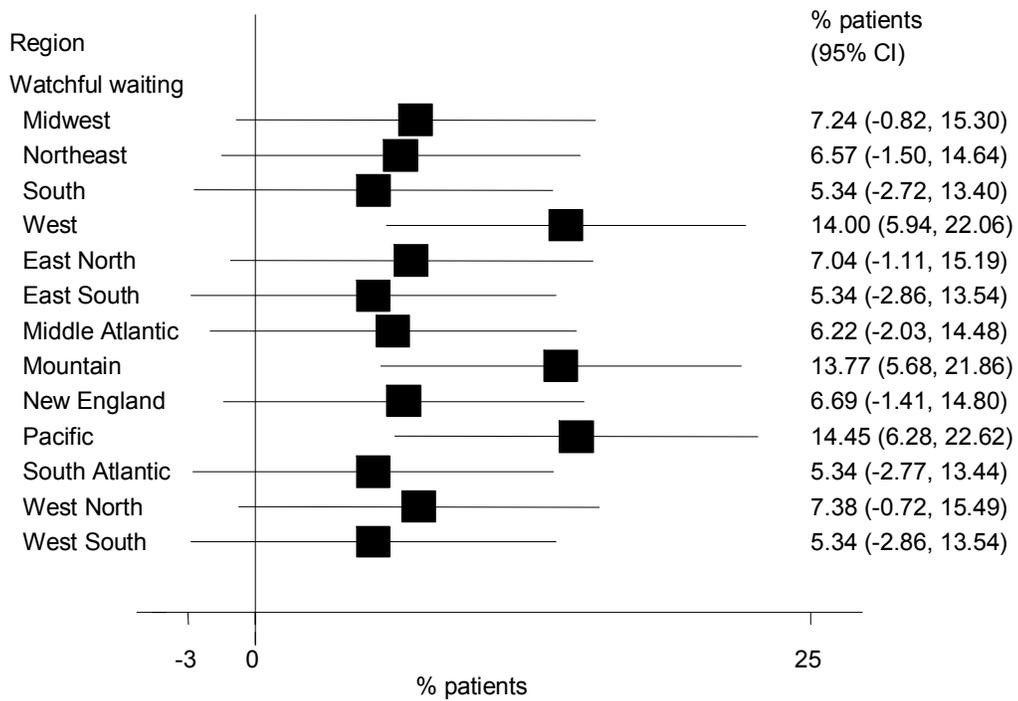


Table C62. Significant variations in proportion of patients treated with watchful waiting

Region		Mean Differences	Lower 95% CI	Upper 95% CI	p Value
East North	Mountain	-6.73	-8.40	-5.07	<0.01
East North	Pacific	-7.41	-9.36	-5.47	<0.01
East North	South Atlantic	1.70	0.04	3.36	0.04
East South	Mountain	-8.43	-10.34	-6.53	<0.01
East South	Pacific	-9.11	-11.27	-6.96	<0.01
East South	West North	-2.04	-4.02	-0.07	0.04
Middle Atlantic	Mountain	-7.55	-9.67	-5.43	<0.01
Middle Atlantic	Pacific	-8.23	-10.58	-5.89	<0.01
Mountain	New England	7.08	5.57	8.59	<0.01
Mountain	South Atlantic	8.43	6.99	9.88	<0.01
Mountain	West North	6.39	4.88	7.90	<0.01
Mountain	West South	8.43	6.53	10.34	<0.01
New England	Pacific	-7.76	-9.60	-5.92	<0.01
Pacific	South Atlantic	9.11	7.36	10.87	<0.01
Pacific	West North	7.07	5.23	8.91	<0.01
Pacific	West South	9.11	6.96	11.27	<0.01
South Atlantic	West North	-2.04	-3.58	-0.51	0.01
West North	West South	2.04	0.07	4.02	0.04
Midwest	South	1.90	0.77	3.03	<0.01
Midwest	West	-6.76	-7.92	-5.60	<0.01
Northeast	South	1.23	0.01	2.44	0.05
Northeast	West	-7.43	-8.67	-6.19	<0.01
South	West	-8.66	-9.76	-7.55	<0.01

Figure C24. Percentage of patients with prostate cancer treated with brachytherapy as an initial therapy in U.S. regions (pooled analysis)

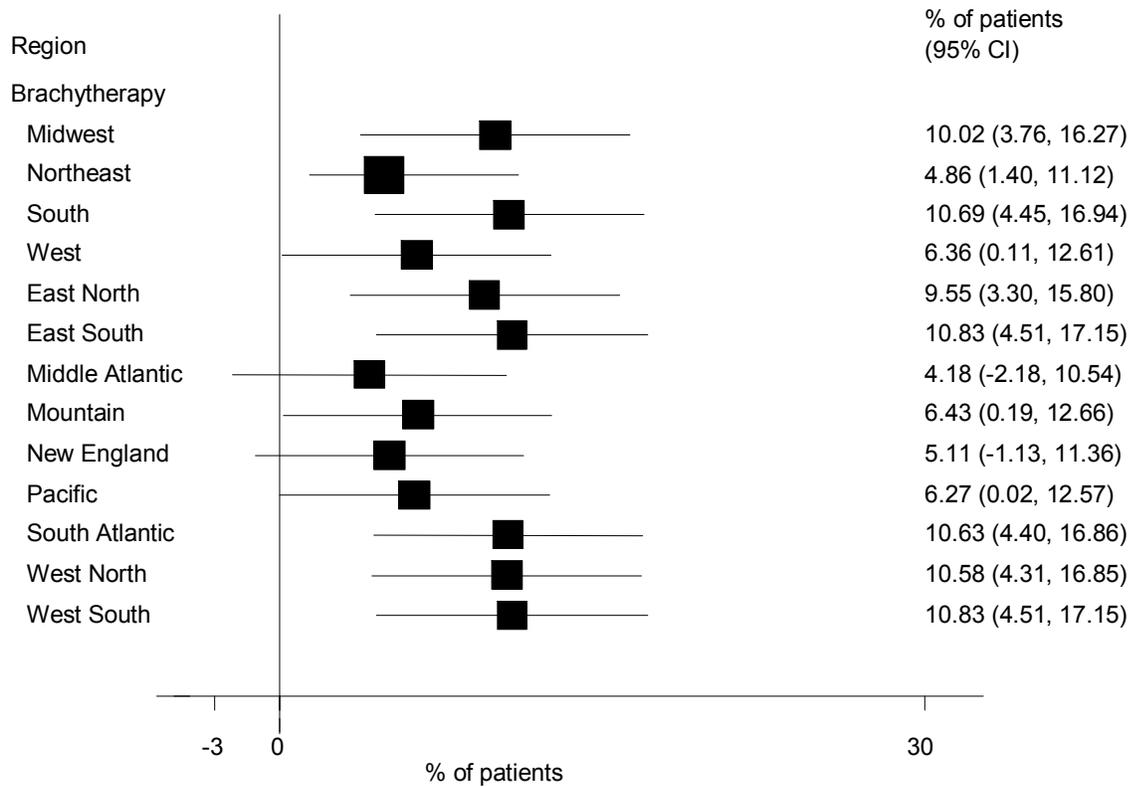


Table C63. Significant variations in proportion of patients treated with brachytherapy

Region		Mean Differences	Lower 95% CI	Upper 95% CI	P Value
East North	Middle Atlantic	5.37	3.66	7.08	<0.01
East North	Mountain	3.12	1.95	4.29	<0.01
East North	New England	4.44	3.21	5.66	<0.01
East North	Pacific	3.27	1.83	4.72	<0.01
East South	Middle Atlantic	6.65	4.74	8.55	<0.01
East South	Mountain	4.40	2.93	5.87	<0.01
East South	New England	5.71	4.20	7.23	<0.01
East South	Pacific	4.55	2.88	6.22	<0.01
Middle Atlantic	Mountain	-2.25	-3.88	-0.61	0.01
Middle Atlantic	Pacific	-2.10	-3.91	-0.28	0.02
Middle Atlantic	South Atlantic	-6.45	-8.07	-4.84	<0.01
Middle Atlantic	West North	-6.40	-8.12	-4.68	<0.01
Middle Atlantic	West South	-6.65	-8.55	-4.74	<0.01
Mountain	New England	1.31	0.19	2.44	0.02
Mountain	South Atlantic	-4.21	-5.25	-3.16	<0.01
Mountain	West North	-4.15	-5.37	-2.93	<0.01
Mountain	West South	-4.40	-5.87	-2.93	<0.01
New England	South Atlantic	-5.52	-6.63	-4.41	<0.01
New England	West North	-5.47	-6.74	-4.19	<0.01
New England	West South	-5.71	-7.23	-4.20	<0.01
Pacific	South Atlantic	-4.36	-5.70	-3.02	<0.01
Pacific	West North	-4.30	-5.76	-2.85	<0.01
Pacific	West South	-4.55	-6.22	-2.88	<0.01
Midwest	Northeast	5.16	4.19	6.12	<0.01
Midwest	West	3.66	2.76	4.55	<0.01
Northeast	South	-5.83	-6.74	-4.92	<0.01
Northeast	West	-1.50	-2.45	-0.55	<0.01
South	West	4.33	3.50	5.16	<0.01

Figure C25. Percentage of patients with prostate cancer treated with primary androgen deprivation as an initial therapy in U.S. regions (pooled analysis)

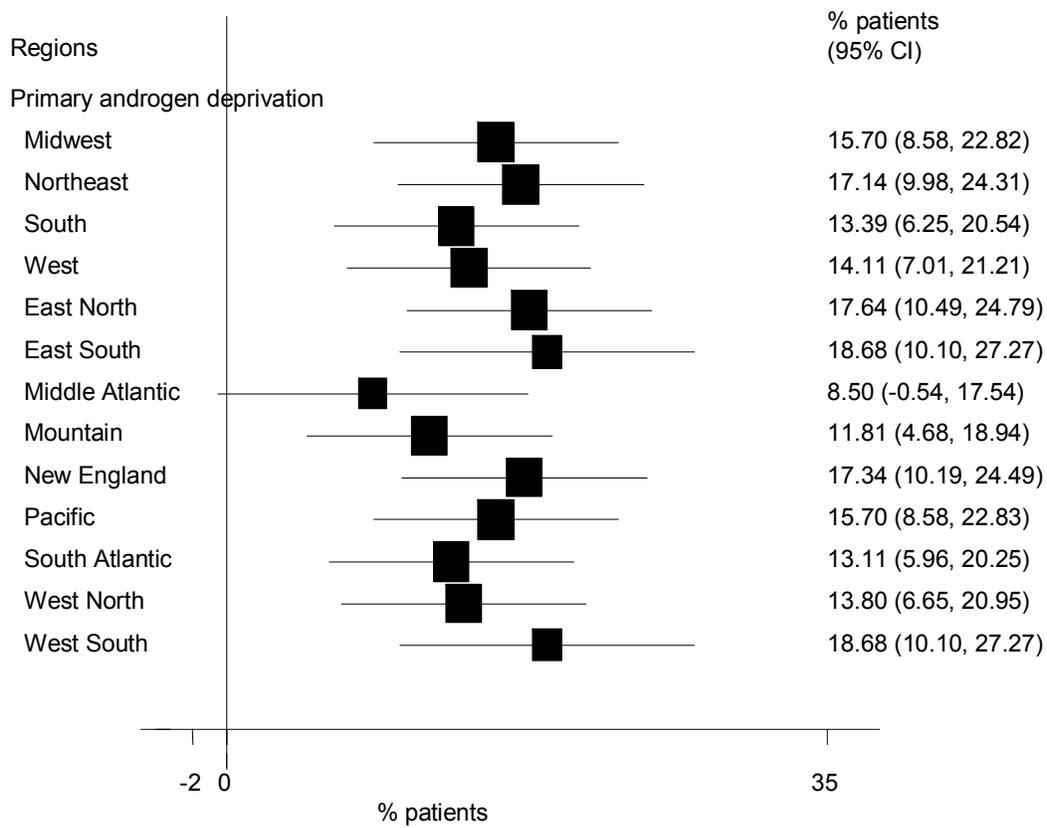


Table C64. Significant variations in proportion of patients treated with primary androgen deprivation

Region		Mean Differences	Lower 95% CI	Upper 95% CI	P Value
East North	Middle Atlantic	9.14	3.26	15.02	<0.01
East North	Mountain	5.83	4.81	6.85	<0.01
East North	Pacific	1.94	0.97	2.90	<0.01
East North	South Atlantic	4.53	3.37	5.70	<0.01
East North	West North	3.84	2.67	5.01	<0.01
East South	Middle Atlantic	10.18	2.72	17.65	<0.01
East South	Mountain	6.87	1.74	12.01	0.01
East South	South Atlantic	5.57	0.43	10.72	0.03
Middle Atlantic	New England	-8.84	-14.72	-2.96	<0.01
Middle Atlantic	Pacific	-7.20	-13.06	-1.35	0.02
Middle Atlantic	West South	-10.18	-17.65	-2.72	<0.01
Mountain	New England	-5.53	-6.55	-4.52	<0.01
Mountain	Pacific	-3.89	-4.66	-3.13	<0.01
Mountain	South Atlantic	-1.30	-2.31	-0.29	0.01
Mountain	West North	-1.99	-3.01	-0.97	<0.01
Mountain	West South	-6.87	-12.01	-1.74	<0.01
New England	Pacific	1.64	0.68	2.60	<0.01
New England	South Atlantic	4.23	3.07	5.40	<0.01
New England	West North	3.54	2.38	4.71	<0.01
Pacific	South Atlantic	2.59	1.64	3.55	<0.01
Pacific	West North	1.90	0.94	2.86	<0.01
South Atlantic	West South	-5.57	-10.72	-0.43	0.03
West North	West South	-4.88	-10.04	0.27	0.06
Midwest	South	2.30	0.77	3.84	<0.01
Midwest	West	1.59	0.51	2.67	<0.01
Northeast	South	3.75	1.98	5.52	<0.01
Northeast	West	3.03	1.64	4.43	<0.01

Figure C26. Relative risk of primary androgen deprivation as an initial therapy (polled analysis)

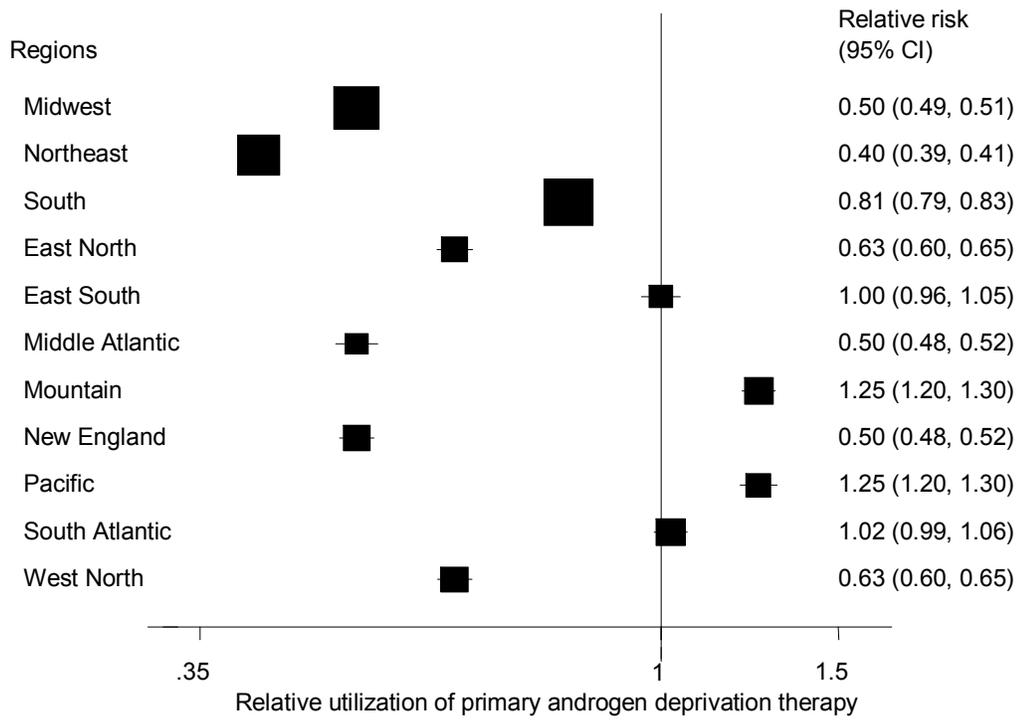


Figure C27. Percentage of patients with localized prostate cancer treated with radical prostatectomy as an initial therapy in the U.S. regions (pooled analysis)

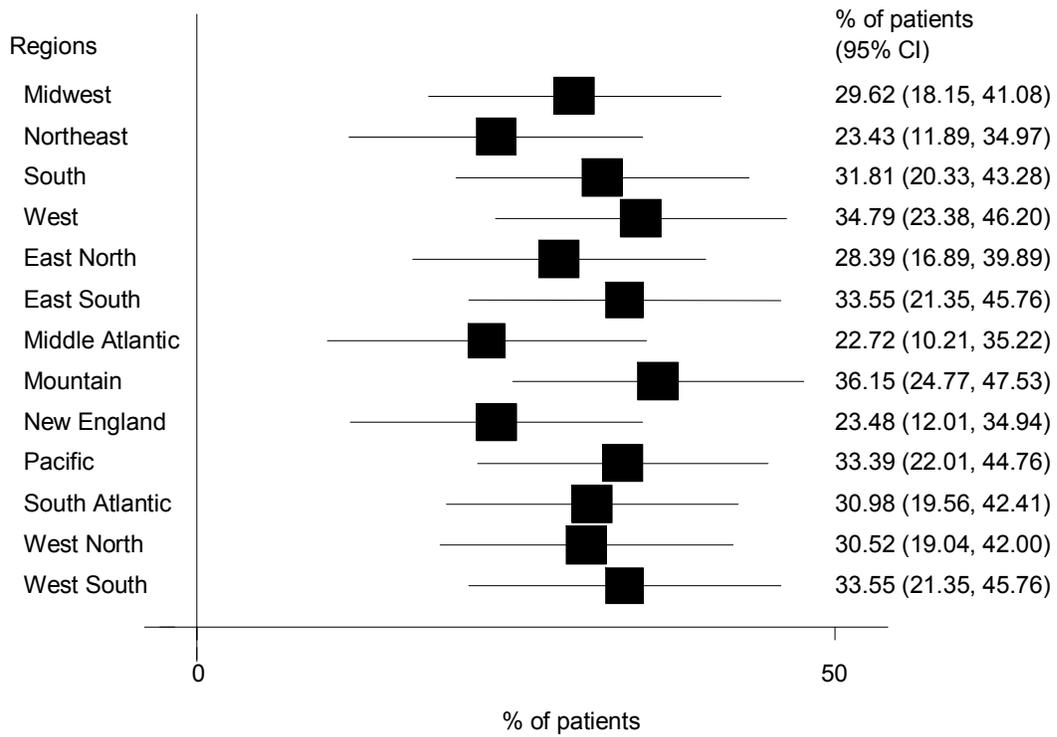


Table C65. Significant variations in proportion of patients treated with radical prostatectomy

Region		Mean	Lower 95% CI	Upper 95% CI	P Value
Midwest	Northeast	6.19	3.26	9.12	<0.01
Midwest	West	-5.17	-7.45	-2.90	<0.01
Northeast	South	-8.38	-11.34	-5.41	<0.01
Northeast	West	-11.36	-14.06	-8.66	<0.01
South	West	-2.99	-5.41	-0.57	0.02
East North	Mountain	-7.76	-11.05	-4.47	<0.01
East North	New England	4.91	1.29	8.54	0.01
East North	Pacific	-5.00	-8.18	-1.82	<0.01
East South	Middle Atlantic	10.84	3.59	18.08	<0.01
East South	New England	10.08	4.63	15.53	<0.01
Middle Atlantic	Mountain	-13.43	-19.39	-7.48	<0.01
Middle Atlantic	Pacific	-10.67	-16.60	-4.74	<0.01
Middle Atlantic	South Atlantic	-8.27	-14.22	-2.31	0.01
Middle Atlantic	West North	-7.80	-13.90	-1.70	0.01
Middle Atlantic	West South	-10.84	-18.08	-3.59	<0.01
Mountain	New England	12.68	9.46	15.90	<0.01
Mountain	Pacific	2.76	0.08	5.45	0.04
Mountain	South Atlantic	5.17	2.14	8.19	<0.01
Mountain	West North	5.63	2.41	8.85	<0.01
New England	Pacific	-9.91	-13.03	-6.80	<0.01
New England	South Atlantic	-7.51	-10.87	-4.15	<0.01
New England	West North	-7.05	-10.60	-3.49	<0.01
New England	West South	-10.08	-15.53	-4.63	<0.01

Table C66. Geographic variations in radical prostatectomy. Age adjusted Rate/100,000 male population (pooled analysis)

Region	Mean	Lower 95% CI	Upper 95% CI
New England	63.63	29.41	156.68
Northeast	67	25.46	159.45
Middle Atlantic	102.02	3.02	207.07
East North	117	23.95	210.05
East South	118.84	14.8	222.88
Midwest	120.78	28.56	213.01
West North	125.95	31.83	220.07
West South	127.9	23.86	231.94
South	129.25	36.96	221.54
South Atlantic	129.5	36.52	222.48
Pacific	150.24	57.18	243.3
West	156.43	64.4	248.45
Mountain	159.57	66.79	252.34
USA	121.79	28.5	215.09

Table C67. Significant differences in age adjusted rate/100,000 male population (pooled analysis)

Region		Mean	Lower 95% CI	Upper 95% CI	P Value
Midwest	Northeast	53.79	36.61	70.97	<0.01
Midwest	West	-35.64	-49.74	-21.55	<0.01
Northeast	South	-62.25	-80.24	-44.27	<0.01
Northeast	West	-89.43	-105.38	-73.49	<0.01
Northeast	USA	-55.98	-75.36	-36.61	<0.01
South	West	-27.18	-42.76	-11.59	<0.01
West	USA	33.45	16.50	50.40	<0.01
East North	Mountain	-42.57	-60.36	-24.77	<0.01
East North	New England	53.37	34.30	72.44	<0.01
East North	Pacific	-33.24	-52.67	-13.81	<0.01
East South	New England	55.21	2.78	107.64	0.04
Middle Atlantic	Mountain	-57.54	-111.42	-3.67	0.04
Mountain	New England	95.93	78.16	113.71	<0.01
Mountain	South Atlantic	30.07	12.39	47.74	<0.01
Mountain	West North	33.62	10.36	56.88	<0.01
Mountain	USA	37.78	19.38	56.17	<0.01
New England	Pacific	-86.61	-106.02	-67.20	<0.01
New England	South Atlantic	-65.87	-84.82	-46.91	<0.01
New England	West North	-62.32	-87.00	-37.64	<0.01
New England	West South	-64.27	-116.70	-11.83	0.02
New England	USA	-58.16	-77.80	-38.52	<0.01
Pacific	South Atlantic	20.74	1.43	40.06	0.04
Pacific	West North	24.29	0.90	47.68	0.04
Pacific	USA	28.45	8.44	48.46	0.01

Figure C28. Age adjusted rate of radical prostatectomy per 100,000 male population (results from individual studies)

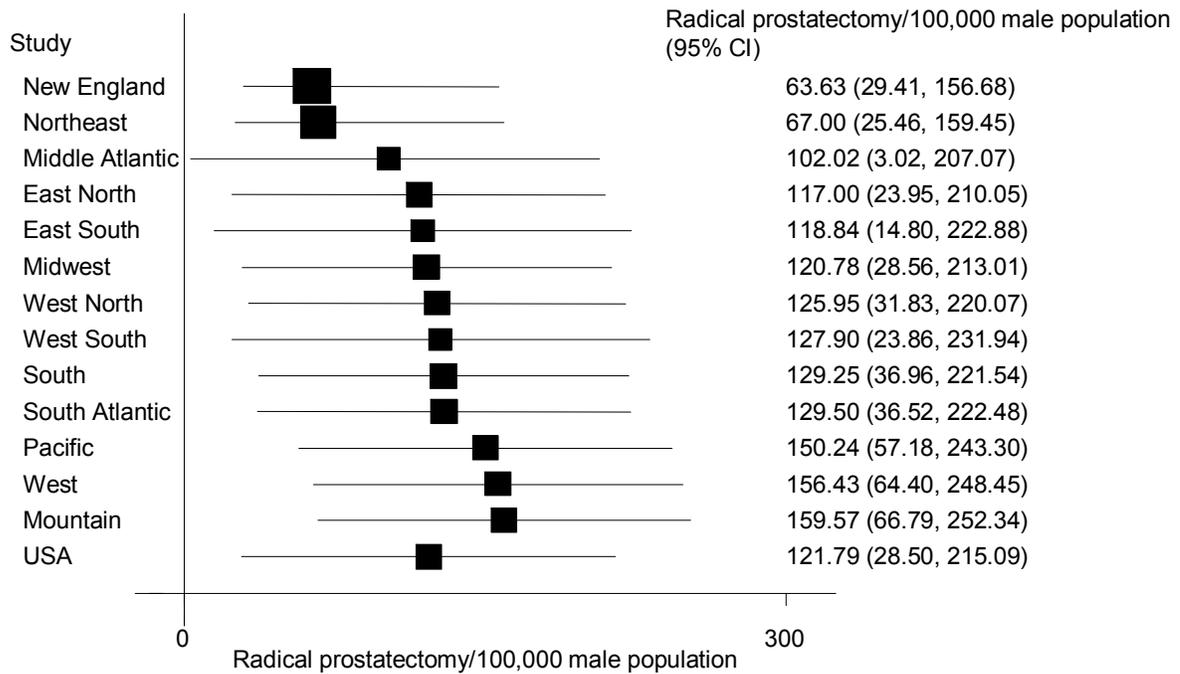


Table C68. Differences in utilization of radical prostatectomy compared with the national average (pooled analysis)

Region	Relative Risk	Lower 95% CI	Upper 95% CI	P Value
Midwest	1.08	0.93	1.25	0.33
Northeast	0.65	0.56	0.75	<0.01
South	1.05	0.91	1.21	0.53
West	1.38	1.19	1.60	<0.01
USA	1.00			

Table C69. Length of hospital stay after radical prostatectomy

Region	Mean	Lower 95% CI	Upper 95% CI	
West	3.7	1.6	5.8	A
Midwest	4.6	2.6	6.7	B
South	4.7	2.7	6.8	B
Northeast	5.2	3.1	7.3	B
USA	4.6	2.1	7	AB

Different letters assigned for statistically significant differences at 95% confidence level

Figure C29. Length of stay in hospital after radical prostatectomy in U.S. regions (pooled analysis)

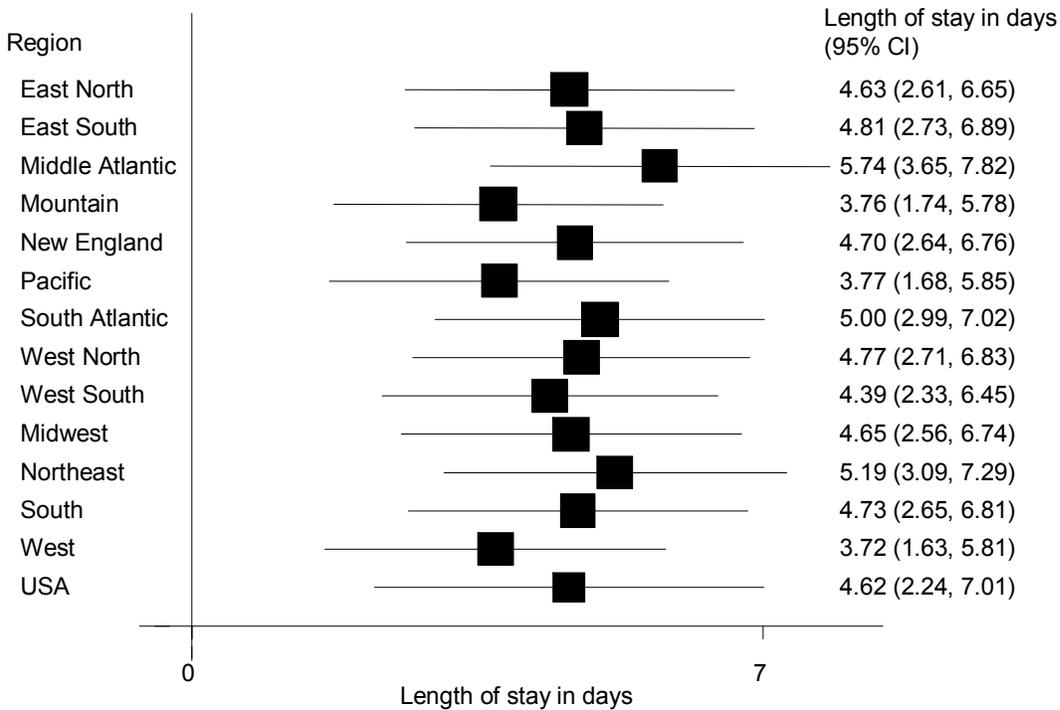


Table C70. Cost of radical prostatectomy in \$ U.S.

Region	Mean	Lower 95% CI	Upper 95% CI
West*	16,043	13,767	18,319
South	16,672	14,872	18,472
Midwest	17,718	15,548	19,888
Northeast*	20,003	17,284	22,722
USA	18,680	11,488	25,872

*statistically significant differences at 95% confidence level

Table C71. Differences in hospital charges for radical prostatectomy in U.S. regions

Region		Differences	Lower 95% CI	Upper 95% CI
Midwest	Northeast	-2,285	-5,762	1,192
Midwest	South	1,046	-1,770	3,863
Midwest	West	1,675	-1,467	4,817
Midwest	USA	-962	-8,473	6,549
Northeast*	South	3,331	72	6,590
Northeast*	West	3,960	416	7,504
Northeast	USA	1,323	-6,365	9,011
South	West	629	-2,270	3,528
South	USA	-2,008	-9,421	5,404
West	USA	-2,637	-10,179	4,905
East North	East South	3,333	-1,314	7,979
East North	Middle Atlantic	-3,480	-8,126	1,166
East North	Mountain	2,595	-1,561	6,751
East North	New England	-1,352	-6,442	3,738
East North	Pacific	-413	-5,059	4,234
East North	South Atlantic	-288	-4,293	3,717
East North	West North	-623	-4,982	3,736
East North	West South	179	-4,180	4,538
East North	USA	-1245	-9,020	6,530
East South*	Middle Atlantic	-6,813	-11,902	-1,723
East South	Mountain	-738	-5,384	3,909
East South	New England	-4,684	-10,182	814
East South	Pacific	-3,745	-8,835	1,345
East South	South Atlantic	-3,620	-8,132	891
East South	West North	-3,956	-8,784	873
East South	West South	-3,154	-7,982	1,675
East South	USA	-4,578	-12,625	3,470
Middle Atlantic*	Mountain	6,075	1,429	10,721
Middle Atlantic	New England	2,128	-3,369	7,626
Middle Atlantic	Pacific	3,068	-2,022	8,157
Middle Atlantic	South Atlantic	3,192	-1,320	7,704
Middle Atlantic	West North	2,857	-1,972	7,686
Middle Atlantic	West South	3,659	-1,170	8,488
Middle Atlantic	USA	2,235	-5,813	10,283
Mountain	New England	-3,947	-9,037	1,143
Mountain	Pacific	-3,008	-7,654	1,639
Mountain	South Atlantic	-2,883	-6,888	1,122
Mountain	West North	-3,218	-7,577	1,141
Mountain	West South	-2,416	-6,775	1,943
Mountain	USA	-3,840	-11,615	3,935
New England	Pacific	939	-4,559	6,437
New England	South Atlantic	1,064	-3,903	6,031
New England	West North	729	-4,528	5,986
New England	West South	1,531	-3,726	6,788
New England	USA	107	-8,205	8,418
Pacific	South Atlantic	125	-4,387	4,636
Pacific	West North	-211	-5,039	4,618
Pacific	West South	592	-4,237	5,420
Pacific	USA	-833	-8,880	7,215
South Atlantic	West North	-335	-4,550	3,880
South Atlantic	West South	467	-3,748	4,682
South Atlantic	USA	-957	-8,652	6,738
West North	West South	802	-3,751	5,355
West North	USA	-622	-8,507	7,263
West South	USA	-1,424	-9,309	6,461

Figure C30. Hospital charges for radical prostatectomy in U.S. regions (results from one study)

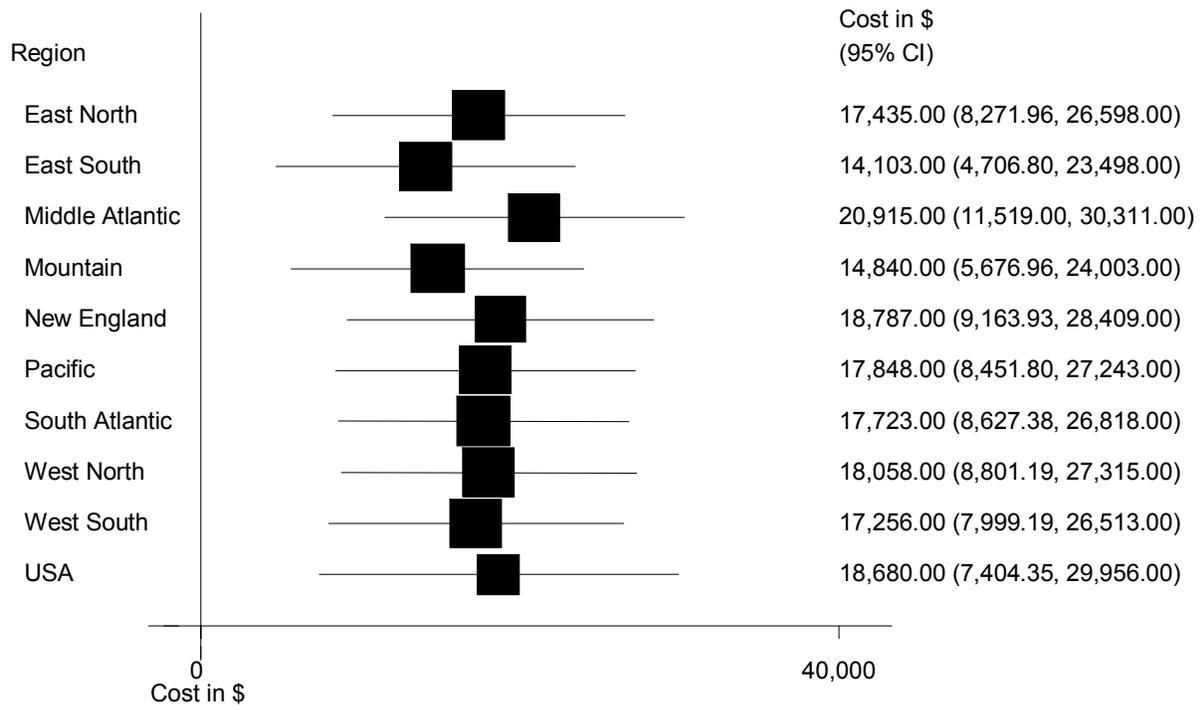


Table C72. Age adjusted mortality from prostate cancer per 100,000 male population in U.S. regions reported in individual studies

Region	Mortality	Lower 95% CI	Upper 95% CI
East North			
Kafadar, 1997 ¹⁰³	29.6	25.7	33.4
CDC, 1999-2004 ¹⁷⁸	38.1	34.7	41.4
Jemal, 2005 ¹⁰⁵	115.6	76.7	154.6
Jemal, 2002 ¹⁰⁴	24.2	21.7	26.6
East South			
Kafadar, 1997 ¹⁰³	27.7	23.5	32.0
CDC, 1999-2004 ¹⁷⁸	45.9	41.7	50.1
Jemal, 2005 ¹⁰⁵	116.2	48.6	183.7
Jemal, 2002 ¹⁰⁴	29.0	24.4	33.7
Middle Atlantic			
Kafadar, 1997 ¹⁰³	29.4	24.4	34.3
CDC, 1999-2004 ¹⁷⁸	36.2	32.0	40.4
Jemal, 2005 ¹⁰⁵	121.5	73.8	169.3
Jemal, 2002 ¹⁰⁴	21.7	13.6	29.8
Mountain			
Kafadar, 1997 ¹⁰³	20.7	17.7	23.7
CDC, 1999-2004 ¹⁷⁸	33.1	30.0	36.2
Jemal, 2002 ¹⁰⁴	100.0	66.2	133.7
Escobedo, 2004 ¹⁰⁶	71.5	48.9	94.0
Jemal, 2005 ¹⁰⁵	22.7	19.4	26.0
New England			
Kafadar, 1997 ¹⁰³	24.9	21.4	28.4
CDC, 1999-2004 ¹⁷⁸	33.3	29.8	36.7
Jemal, 2005 ¹⁰⁵	101.5	67.8	135.3
Escobedo, 2004 ¹⁰⁶	84.2	61.6	106.7
Jemal, 2002 ¹⁰⁴	22.4	19.5	25.2
Pacific			
Kafadar, 1997 ¹⁰³	20.7	15.8	25.7
CDC, 1999-2004 ¹⁷⁸	32.6	28.6	36.6
Jemal, 2005 ¹⁰⁵	101.9	62.9	140.9
Jemal, 2002 ¹⁰⁴	21.8	17.7	25.8
South Atlantic			
Kafadar, 1997 ¹⁰³	30.9	28.1	33.7
CDC, 1999-2004 ¹⁷⁸	41.9	39.1	44.6
Jemal, 2005 ¹⁰⁵	125.4	95.2	155.6
Jemal, 2002 ¹⁰⁴	29.5	27.6	31.5
West North			
Kafadar, 1997 ¹⁰³	24.6	21.4	27.8
CDC, 1999-2004 ¹⁷⁸	34.5	30.8	38.3
Jemal, 2005 ¹⁰⁵	109.5	66.8	152.2
Escobedo, 2004 ¹⁰⁶	94.7	72.1	117.3
Jemal, 2002 ¹⁰⁴	23.5	20.2	26.8
West South			
Kafadar, 1997 ¹⁰³	26.3	22.0	30.6
CDC, 1999-2004 ^{138,178}	39.6	35.6	43.5
Jemal, 2005 ¹⁰⁵	118.7	51.2	186.2
USA			
CDC, 1999-2004 ¹⁷⁸	36.7	28.5	44.8
Jemal, 2005 ¹⁰⁵	24.4	18.7	30.1

Table C73. Geographic differences in prostate cancer age adjusted mortality per100,000 male population (CDC data, 1999-2004)

Region		Difference	Standard Error	P Value
East North	East South	-7.86	2.74	0.00
East North	Middle Atlantic	1.83	2.74	0.51
East North	Mountain	4.92	2.31	0.03
East North	New England	4.79	2.46	0.05
East North	Pacific	5.43	2.66	0.04
East North	South Atlantic	-3.81	2.22	0.09
East North	West North	3.50	2.56	0.17
East North	West South	-1.51	2.64	0.57
East North	USA	1.36	4.49	0.76
East South	Middle Atlantic	9.69	3.04	0.00
East South	Mountain	12.78	2.65	<0.01
East South	New England	12.65	2.78	<0.01
East South	Pacific	13.30	2.96	<0.01
East South	South Atlantic	4.05	2.57	0.12
East South	West North	11.36	2.87	<0.01
East South	West South	6.35	2.95	0.03
East South	USA	9.22	4.68	0.05
Middle Atlantic	Mountain	3.09	2.65	0.24
Middle Atlantic	New England	2.97	2.78	0.29
Middle Atlantic	Pacific	3.61	2.96	0.22
Middle Atlantic	South Atlantic	-5.63	2.57	0.03
Middle Atlantic	West North	1.67	2.87	0.56
Middle Atlantic	West South	-3.34	2.95	0.26
Middle Atlantic	USA	-0.47	4.68	0.92
Mountain	New England	-0.13	2.36	0.96
Mountain	Pacific	0.51	2.57	0.84
Mountain	South Atlantic	-8.73	2.10	<0.01
Mountain	West North	-1.42	2.46	0.56
Mountain	West South	-6.43	2.55	0.01
Mountain	USA	-3.56	4.44	0.42
New England	Pacific	0.64	2.71	0.81
New England	South Atlantic	-8.60	2.27	0.00
New England	West North	-1.29	2.60	0.62
New England	West South	-6.30	2.68	0.02
New England	USA	-3.43	4.52	0.45
Pacific	South Atlantic	-9.24	2.49	0.00
Pacific	West North	-1.93	2.80	0.49
Pacific	West South	-6.95	2.87	0.02
Pacific	USA	-4.08	4.63	0.38
South Atlantic	West North	7.31	2.38	0.00
South Atlantic	West South	2.30	2.46	0.35
South Atlantic	USA	5.17	4.39	0.24
West North	West South	-5.01	2.78	0.07
West North	USA	-2.14	4.57	0.64
West South	USA	2.87	4.62	0.53

Table C74. Significant geographic differences in prostate cancer age adjusted mortality/100,000 among different races (CDC data, 1999-2004)

Region		Difference	Standard Error	p Value
African American				
East North	East South	-9.11	1.50	<0.01
East North	New England	9.37	1.60	<0.01
East North	Pacific	5.90	1.82	0.00
East North	South Atlantic	-8.27	1.27	<0.01
East North	West South	-3.01	1.50	0.05
East South	Middle Atlantic	11.24	1.71	<0.01
East South	Mountain	10.70	1.77	<0.01
East South	New England	18.48	1.71	<0.01
East South	Pacific	15.02	1.91	<0.01
East South	West North	8.94	1.86	<0.01
East South	West South	6.11	1.61	0.00
East South	USA	6.39	2.79	0.02
Middle Atlantic	New England	7.25	1.80	<0.01
Middle Atlantic	South Atlantic	-10.39	1.50	<0.01<.0001
Middle Atlantic	West South	-5.13	1.71	0.00
Mountain	New England	7.78	1.86	<0.01
Mountain	Pacific	4.31	2.05	0.04
Mountain	South Atlantic	-9.86	1.58	<0.01
Mountain	West South	-4.60	1.77	0.01
New England	South Atlantic	-17.64	1.50	<0.01
New England	West North	-9.54	1.94	<0.01
New England	West South	-12.37	1.71	<0.01
New England	USA	-12.09	2.84	<0.01
Pacific	South Atlantic	-14.17	1.73	<0.01
Pacific	West North	-6.08	2.12	0.00
Pacific	West South	-8.91	1.91	<0.01
Pacific	USA	-8.63	2.97	0.00
South Atlantic	West North	8.09	1.67	<0.01
South Atlantic	West South	5.26	1.39	0.00
South Atlantic	USA	5.55	2.67	0.04
Hispanic				
East North	Middle Atlantic	-5.34	2.08	0.01
East North	Mountain	-9.27	1.85	<0.01
East North	New England	-5.74	2.32	0.01
East North	South Atlantic	-5.14	2.08	0.01
East North	West South	-4.77	2.32	0.04
Middle Atlantic	Mountain	-3.93	1.85	0.03
Mountain	Pacific	5.49	2.12	0.01
Mountain	South Atlantic	4.13	1.85	0.03
Mountain	West South	4.50	2.12	0.03
Whites				
Mountain	South Atlantic	2.97	1.12	0.01
New England	South Atlantic	2.39	1.19	0.05
Pacific	South Atlantic	3.37	1.32	0.01

Figure C31. Mortality from prostate cancer (per 100,000 male population) among different races in U.S. regions (CDC data, 1999-2004)

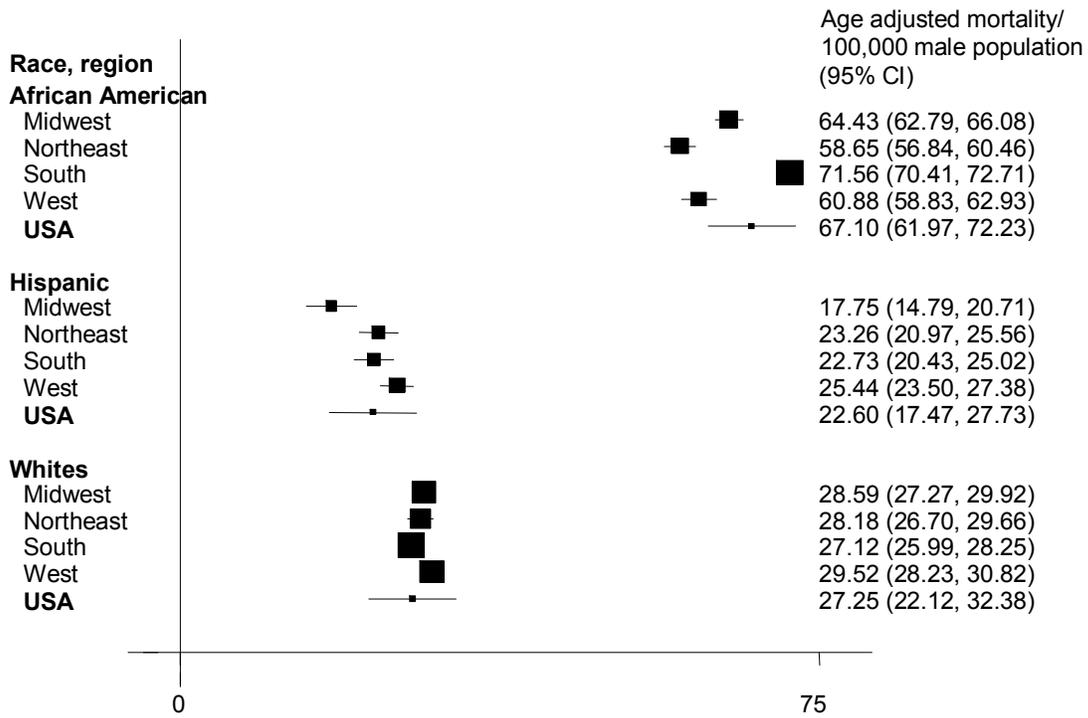


Figure C32. Positive correlation between PSA testing among males older than 40 years and adjusted prostate cancer mortality in the USA. Ecologic analysis

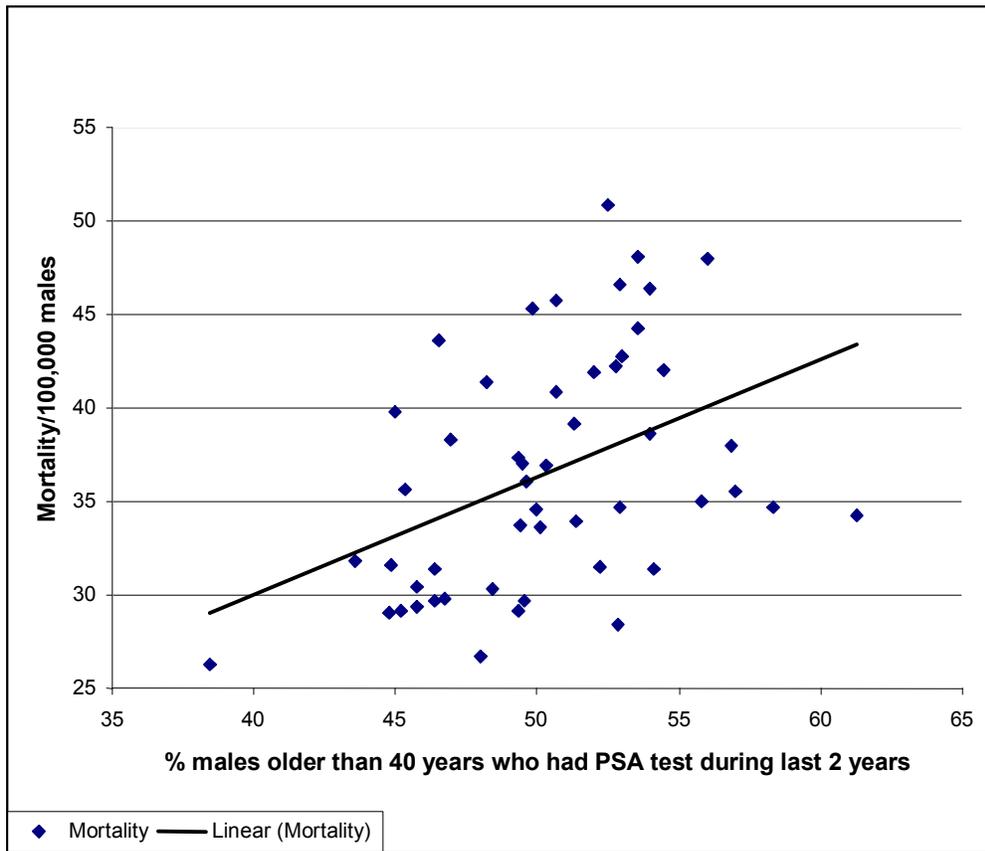


Table C75. Distribution of hospital and surgeon annual volumes of radical prostatectomy

	Hospital Volume	Surgeon Volume
Mean	43.6	12.2
Standard deviation	37.0	13.5
Median	40.0	10.0
Quartile 1	8-22	0.1-3.3
Quartile 2	23-39	3.5-8.75
Quartile 3	40-43	10-14
Quartile 4	>85	15-75.6

Figure C33. Difference in surgery-related death rate corresponding to an increase by 10 radical prostatectomies performed in hospital

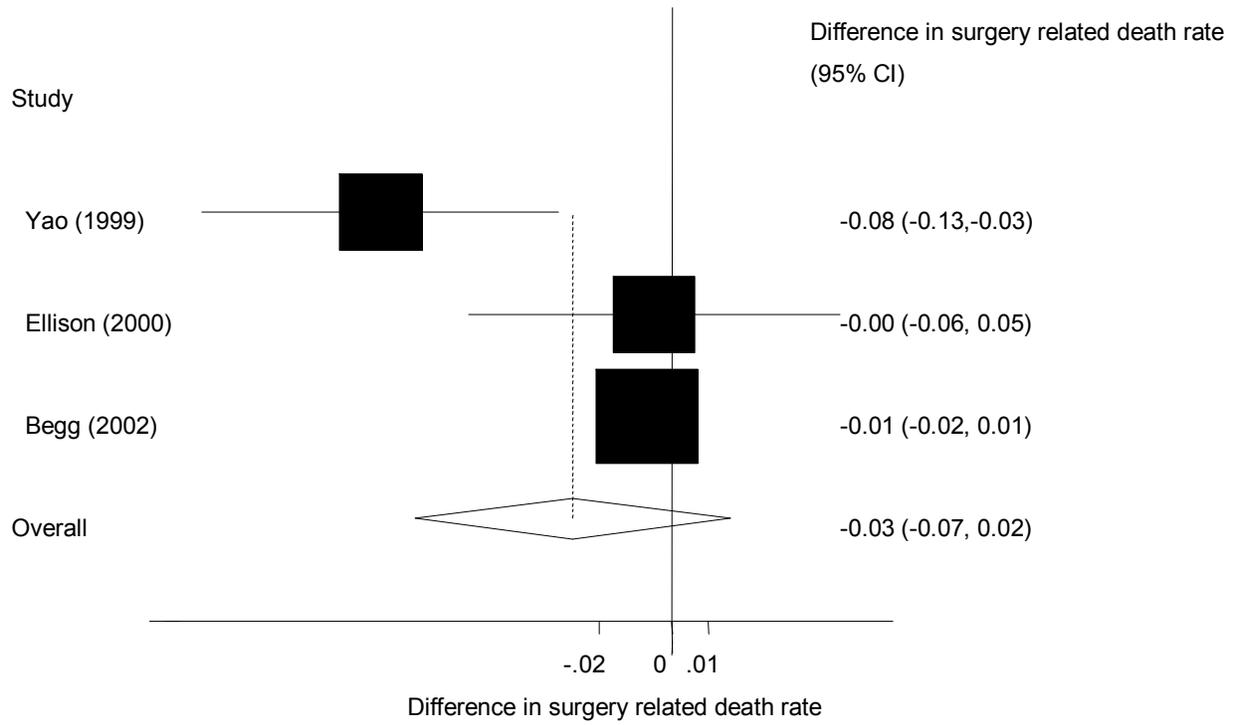


Figure C34. Relative risk of surgery related death corresponding to an increase by 10 radical prostatectomies performed in hospital

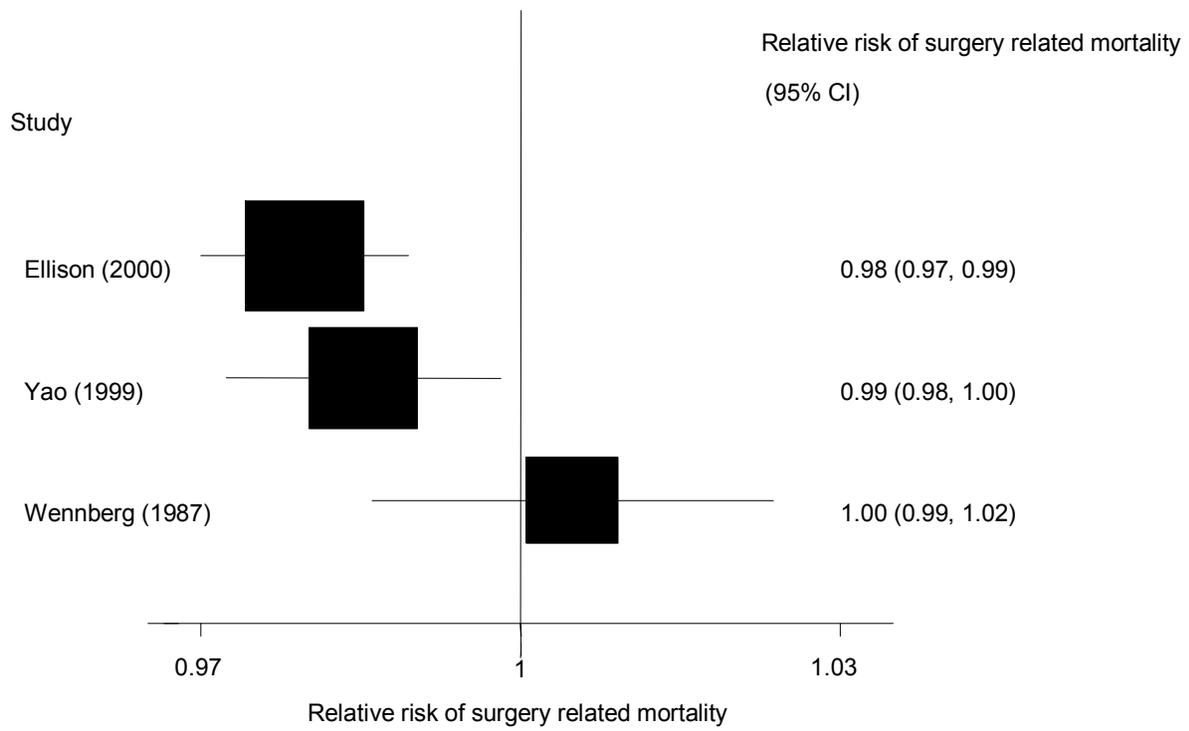


Figure C35. Relative risk of surgery related death in quartile and above and below mean of annual hospital volume (pooled analysis)

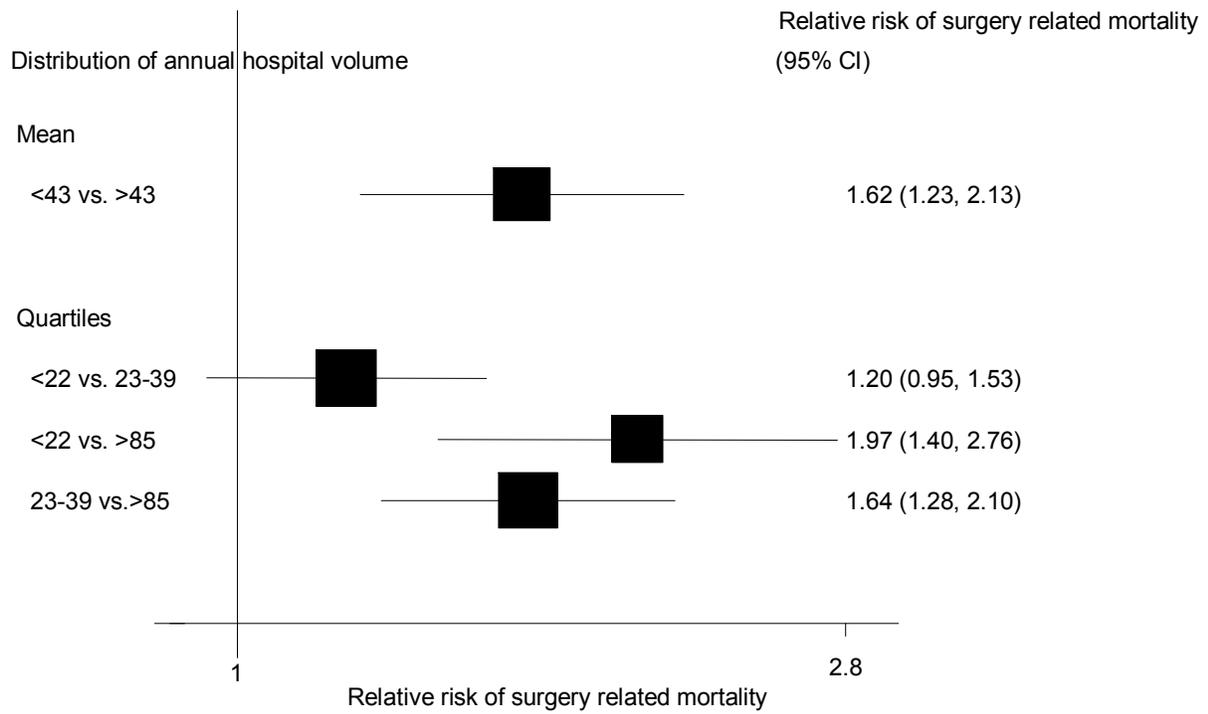


Figure C36. Number of avoided and excessive deaths in quartiles and above and below mean of annual hospital volume (pooled analysis)

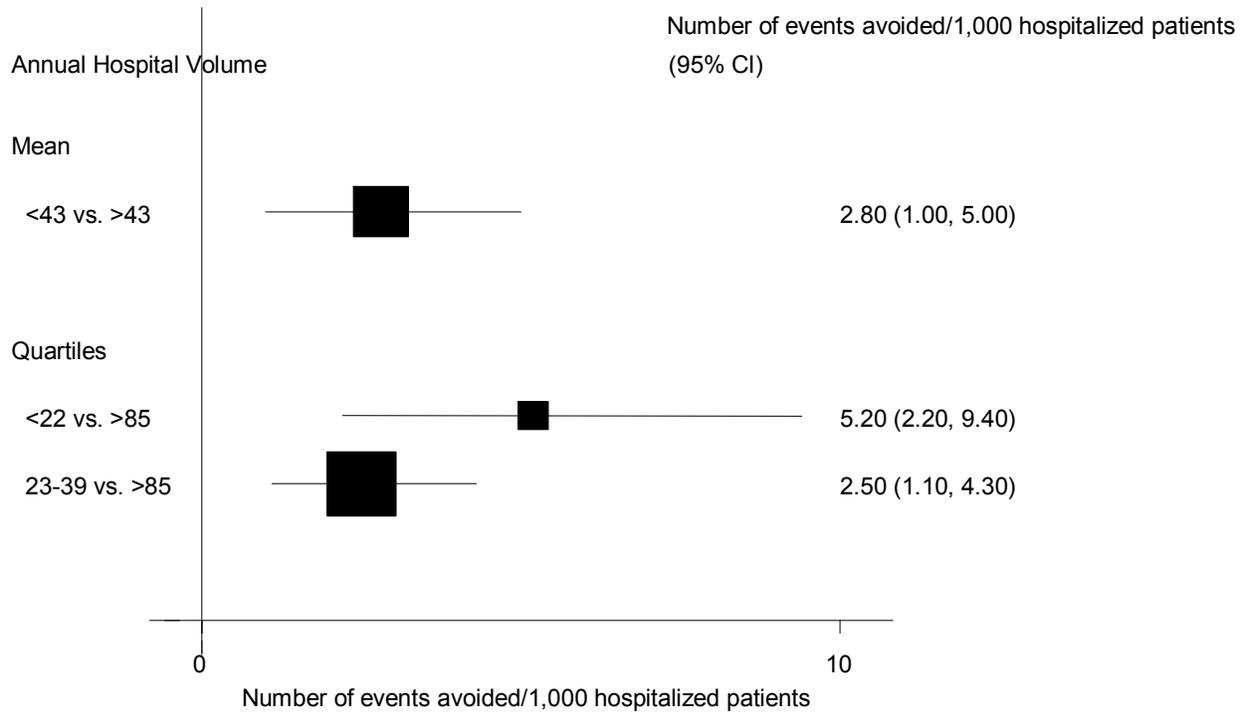


Figure C37. Difference in surgery related complications rate corresponding to an increase by 10 radical prostatectomies performed in hospital

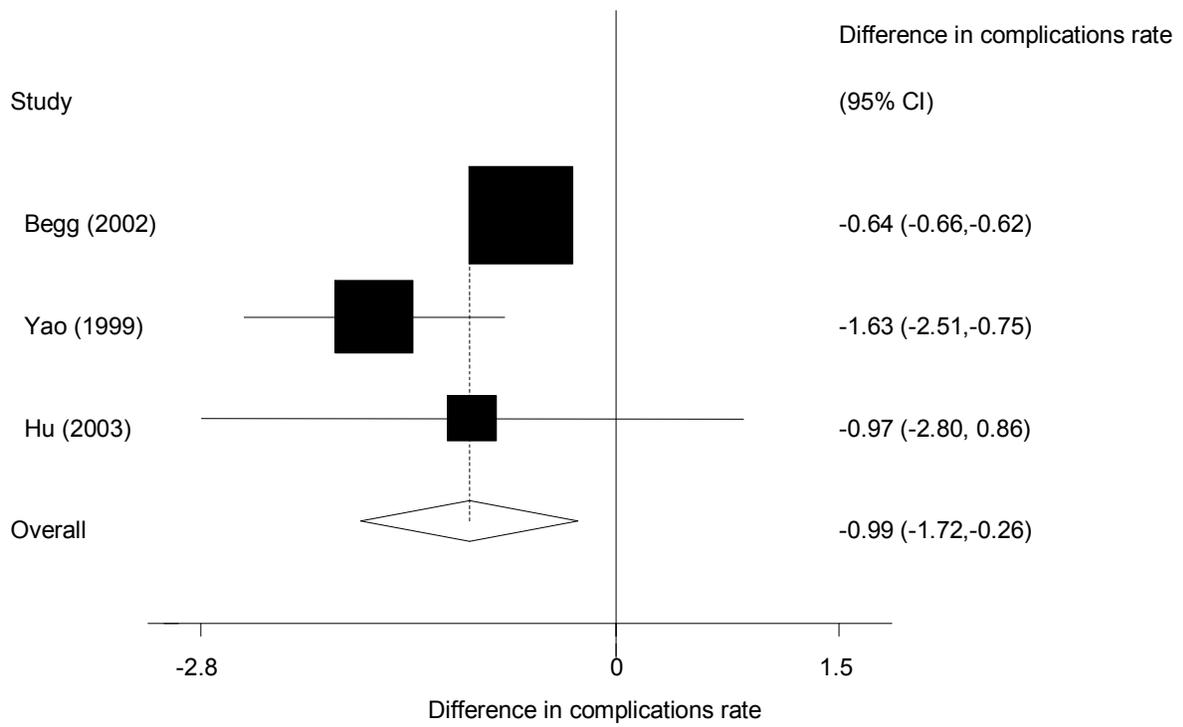


Figure C38. Relative risk of adjuvant therapy 6 months after radical prostatectomy in relation to hospital volume (results from one cohort study)

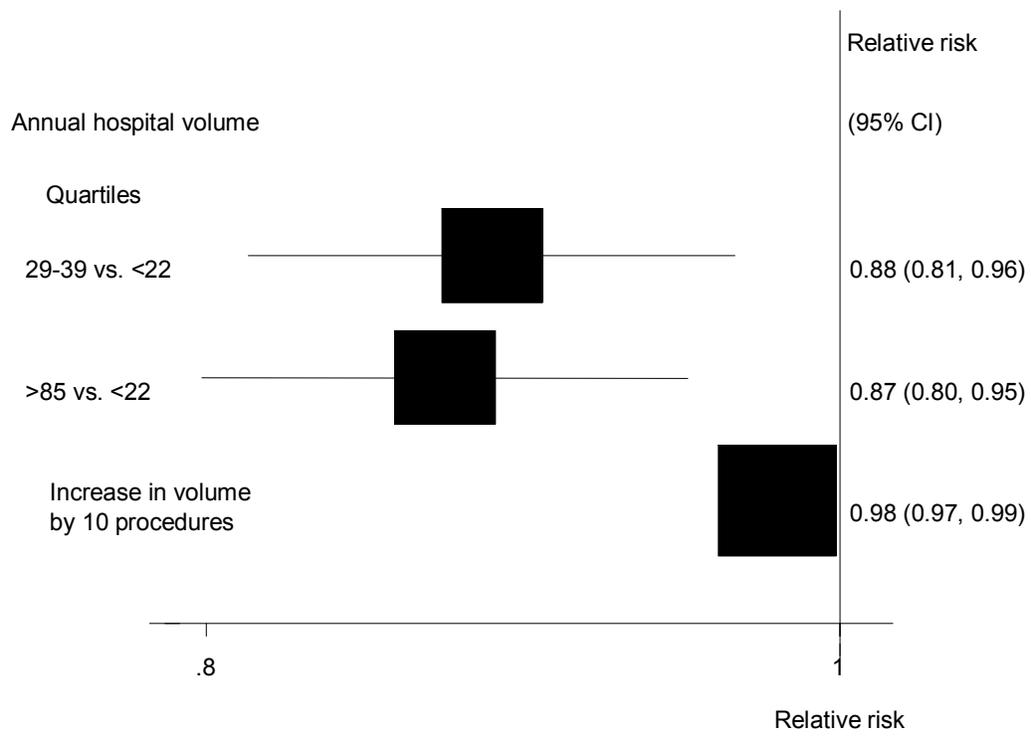


Figure C39. Difference in surgery related complication rates corresponding to an increase by 10 radical prostatectomies performed in hospital

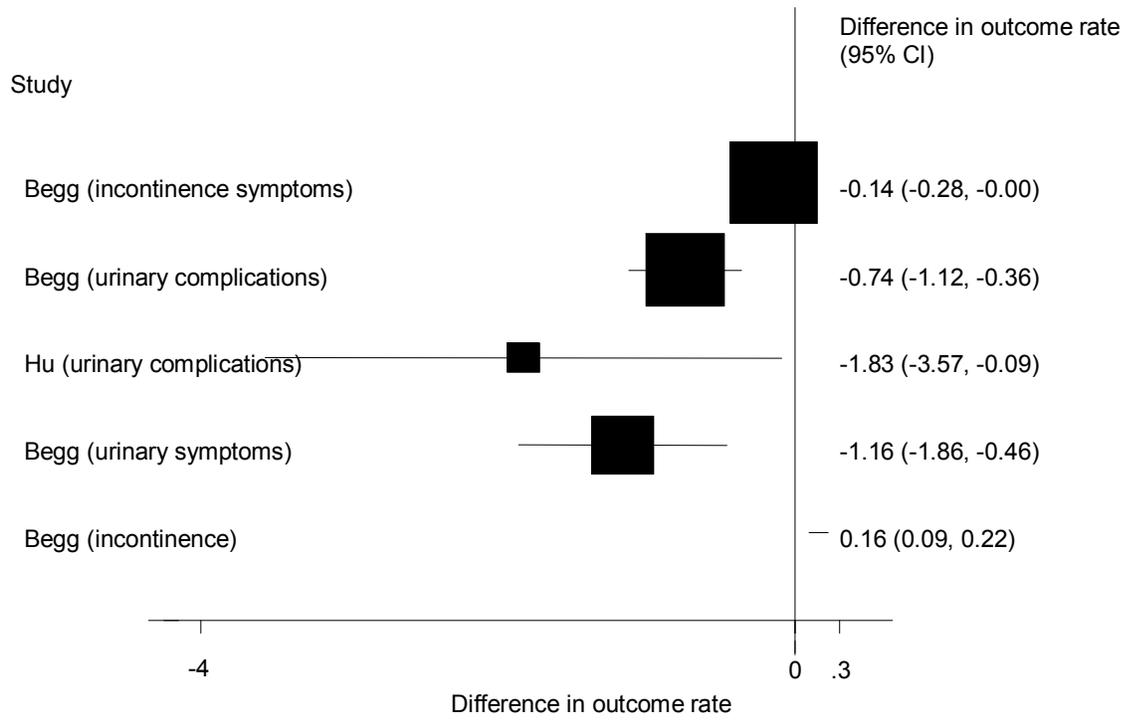
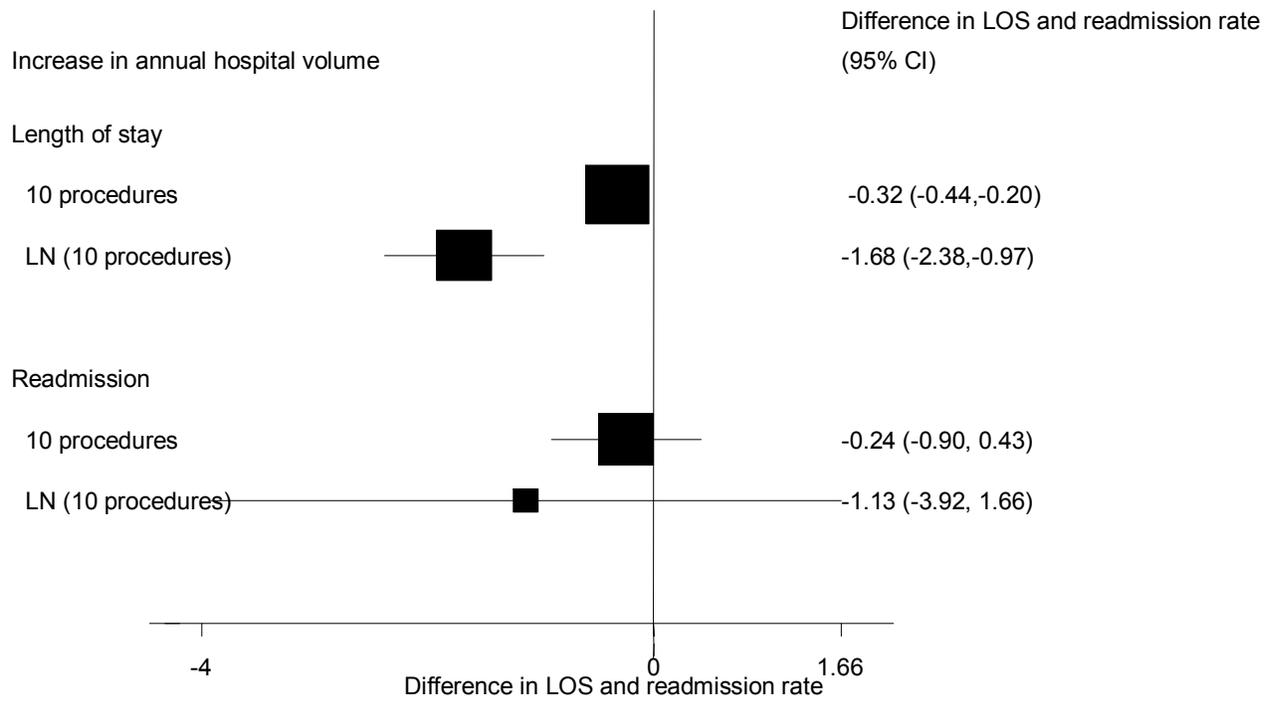


Figure C41. Difference in length of stay and readmission rate corresponding to an increase by ten procedures in annual hospital volume (pooled analysis)



LN = natural logarithm of hospital volume; LOS = length of stay in hospital

Figure C42. Difference in length of stay and readmission rate in categories of hospital volume (pooled analysis)

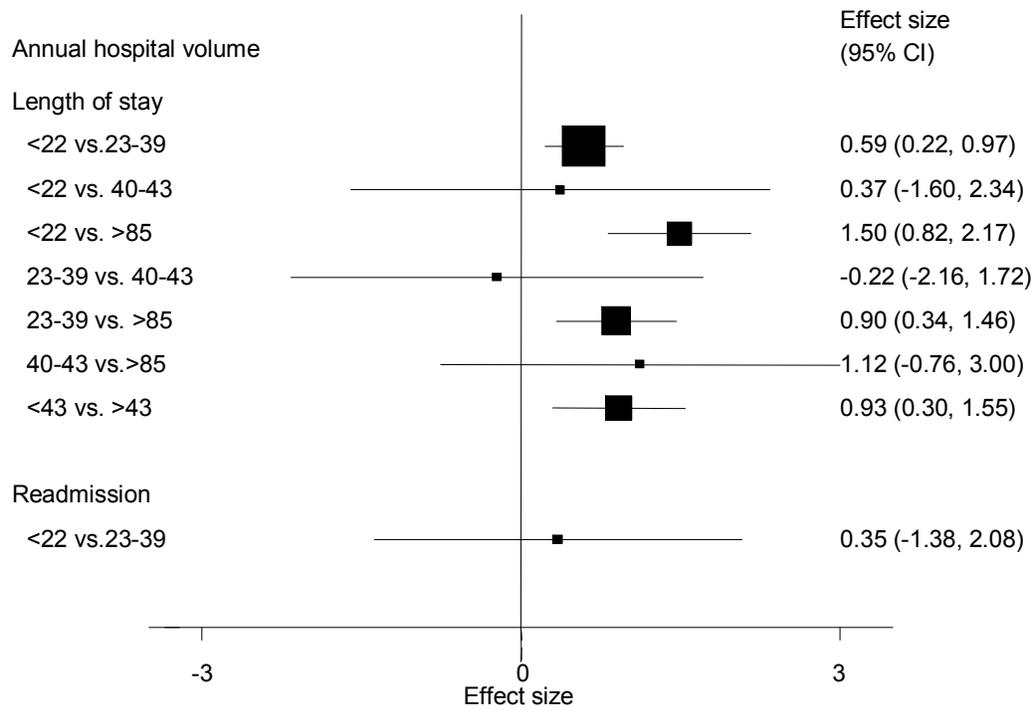


Figure C43. Difference in rates of surgery-related urinary complications, long term incontinence, and positive surgical margins corresponding to an increase by one radical prostatectomy performed by a surgeon (the results from individual studies)

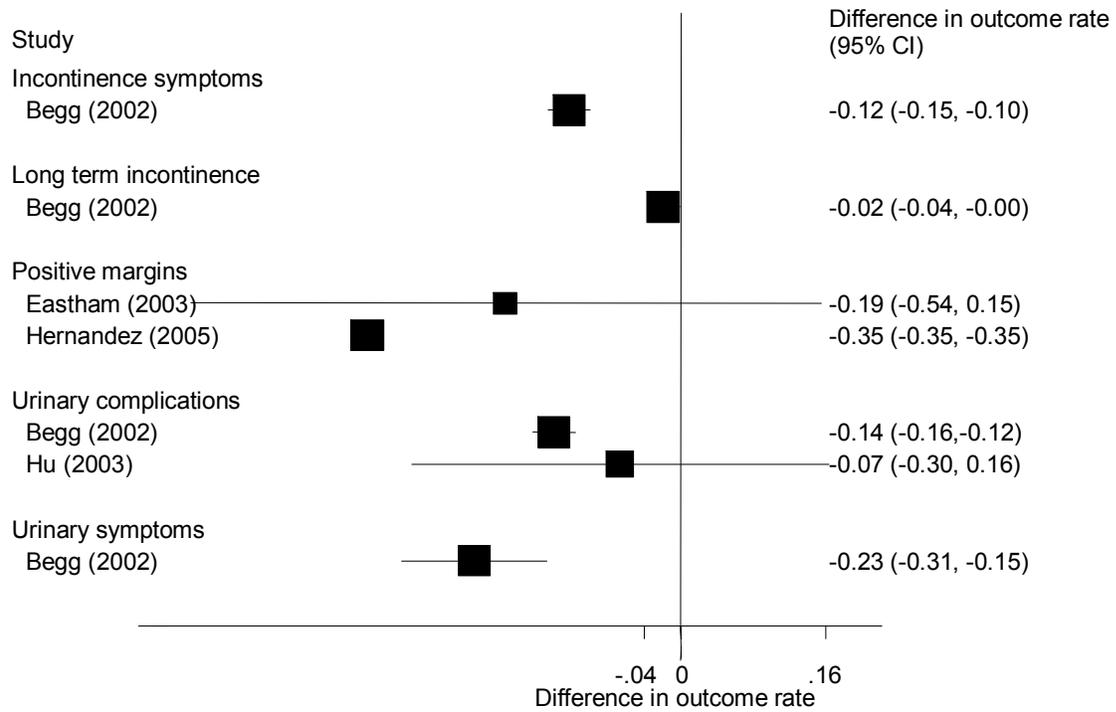


Figure C44. Disease-specific survival at time points by treatment and PSA level (ng/ml)

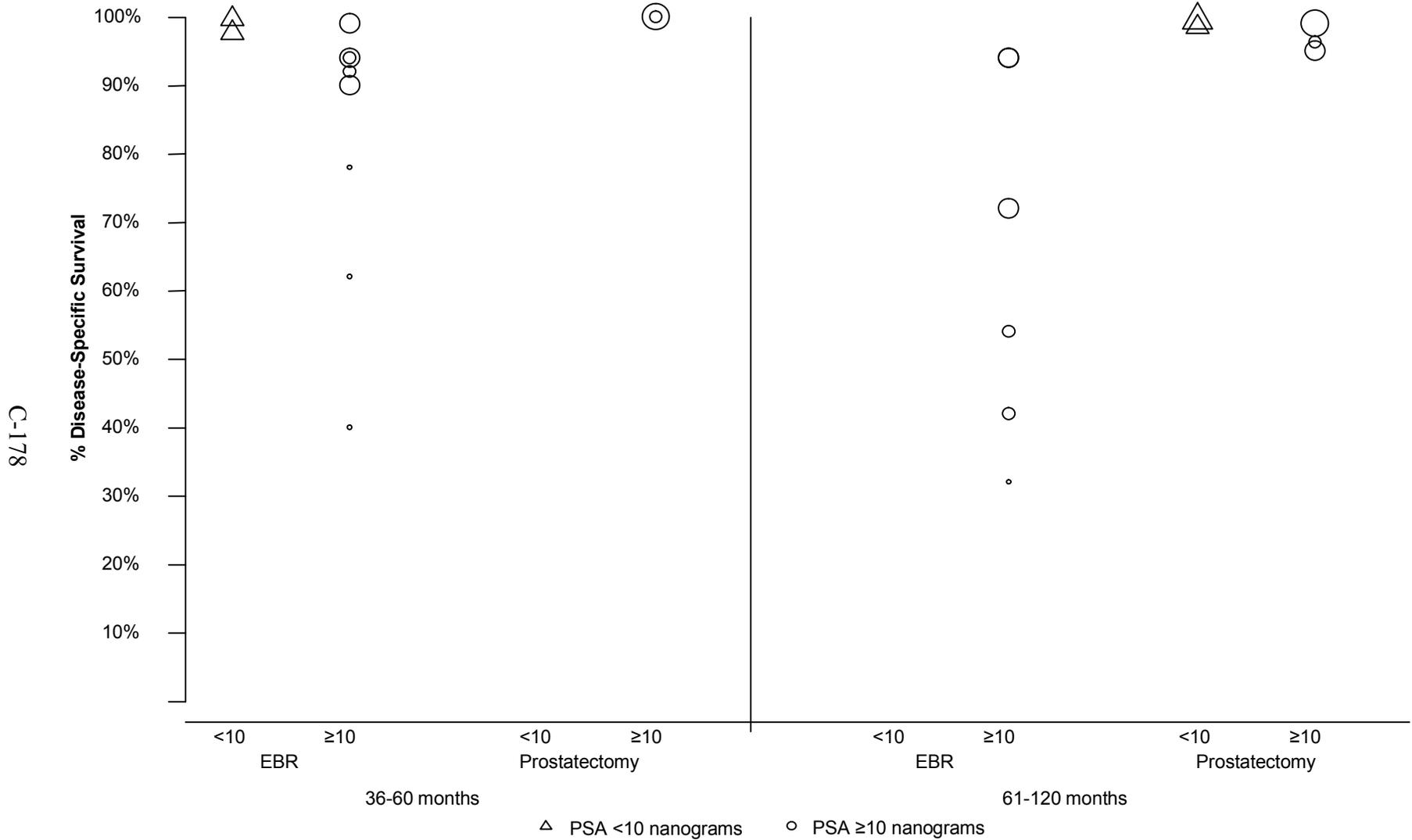


Table C76. Odds ratio and attributable events of clinical outcomes after different treatments | patients with localized prostate cancer

Design	Quality	Studies Reference	Active	Control	Outcomes	Effect: Odds Ratio (95%CI)	Attributable Fraction of Events (%)	Rate (%) in Active Group	Rate (%) in Control Group	NNT	Number of Avoided (Excessive) Events per 1,000 Hospitalized
RCT	Moderate	Bill-Axelsson, 2005 ¹⁷⁹	Radical prostatectomy at 10 years	Watchful waiting at 10 years	Overall mortality	0.74 (0.56 ;0.99)**	26	27	32	20	50
RCT	Moderate	Wirth, 2004 ¹⁹	Bicalutamide and watchful waiting	Placebo and adjuvant therapy	Overall mortality	1.31 (1.04; 1.65)	23.7	30	20	-21	-47
RCT	Moderate	Zietman, 2005 ⁶	External beam radiation: high dose (79.2 Gy)	External beam radiation: conventional dose (70 Gy)	3 consecutive increases in PSA level, with the failure backdated to a point halfway between the first increase and the last non-increasing value	0.40 (0.25; 0.62)	60.5	20	40	5	190
RCT	Moderate	D'Amico, 2004 ⁸	Conformal radiation therapy and androgen suppression therapy	Conformal radiation therapy (70 Gy)	PSA >1.0 ng/ml and increasing >0.2 ng/ml on 2 consecutive visits	0.34 (0.18; 0.63)	66.2	20	40	4	232
RCT	Moderate	Paulson, 1982 ¹³	Radical prostatectomy	Radiation therapy	Acid phosphatase elevation on 2 consecutive followups or by appearance of bony or parenchymal disease with or without concomitant acid phosphatase elevation	0.27 (0.11; 0.71)	72.6	10	40	4	250
RCT	Moderate	Sathya, 2005 ¹⁵	EBRT	Iridium implant + EBRT	PSA failure, clinical failure	3.70 (1.27; 10.73)	72.9	60	30	-3	-315

Table C77. Comparative effectiveness of adverse events after different treatments in patients with localized prostate cancer

Design	Study Quality	Outcomes: Adverse Events and Quality of Life	WW % (n=230)	AD % (n=179)	EBRT/Brachy % (n=583)	RP % (n=1,373)
Large population	Moderate	Satisfied with treatment : delighted/pleased**	17.6/30.8	22.9/40.3	32.1/37.8	22.5/36.1
Large population based	Moderate	Make same decision again: definitely yes*/ probably yes*	51.2/40.8	64.4/30.6	62.4/31.4	56.2/34.5
Large population based	Moderate	Bowel urgency: almost everyday*	0.2	3.3	3.2	0.9
Large population based	Moderate	Urinary leakage: daily or more often*	7	10.8	11.8	34.8
Large population based	Moderate	Erectile dysfunction: no erections at all*	32.5	85.8	42.7	58.4
			n=326, %		n = 376, %	
RCT	Moderate	Erectile dysfunction ^	45		80	
RCT	Moderate	Urinary leakage ^	21		49	
RCT	Moderate	Urinary obstruction ^	44		28	
RCT	Moderate	Diarrhea ^	0.9		5	
RCT	Moderate	Fecal leakage ≥once/week^	7		6	

WW = watchful waiting; AD = androgen deprivation; EBRT/Brachy = external beam radiation/brachytherapy; RP = radical prostatectomy

* PCOS study; ^ Steineck study

Table C78. Odds ratio of outcomes, attributable proportion of events among exposed, number needed to treat to harm one patient, and the number of avoided events per 1000 treated patients: radical prostatectomy vs. watchful waiting

Design	Study Quality	Outcomes	Effect: Odds ratio of events, 95% CI			Attributable Fraction of Events (%)	NNT to Harm	Number of Avoided (Excessive) Events
Large population based study	Moderate	Satisfied with treatment: delighted*	1.34	0.68	2.73	26.4	-20	-49
Large population based study	Moderate	Satisfied with treatment: pleased*	1.27	0.70	2.29	21.2	-19	-53
Large population based study	Moderate	Would make same decision again: definitely yes*	1.22	0.70	2.13	18.2	-20	-50
Large population based study	Moderate	Would make same decision again: probably yes*	0.76	0.43	1.36	-30.9	16	63
Large population based study	Moderate	Bowel urgency: almost every day*	4.53	0.04	580.71	77.9	-143	-7
Large population based study	Moderate	Urinary leakage: daily or more often*	7.09	2.97	16.95	85.9	-4	-278
Large population based study	Moderate	Erectile dysfunction: no erections at all*	2.92	1.64	5.19	65.7	-4	-259
RCT	Moderate	Erectile dysfunction [^]	4.89	2.61	9.17	79.5	-3	-350
RCT	Moderate	Urinary leakage [^]	3.61	1.94	6.72	72.3	-4	-280
RCT	Moderate	Urinary obstruction [^]	0.49	0.28	0.89	-102.0	6	160
RCT	Moderate	Diarrhea [^]	5.79	0.60	55.64	82.7	-24	-41
RCT	Moderate	Fecal leakage \geq once/week [^]	0.85	0.28	2.62	-17.9	100	10

*-PCOS study

[^] Steineck study

References for Appendix C

(Note that reference numbers are different than those in the text of the report)

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Appendix D: List of Excluded Studies

For Key Questions 1, 2, and 4: Excluded studies are available from the American Urological Association Guideline for the Management of Clinically Localized Prostate Cancer Database. (In press.)

There were 13,888 citations retrieved and reviewed. Of these, 1,764 were selected for winnowing; 759 accepted for further review, and 592 articles, judged potentially eligible, underwent an extraction process. The main reasons (and number of rejected articles) for rejection to narrow articles from 1,764 to 759 were: no outcomes data (435) and T3/T2 contamination (401). Upon further review of the 592 potentially eligible articles, 156 were rejected. Reasons for rejection (and number of rejected articles) included: no outcomes data (31); not local disease (38); T1-T2 patients <50 (7); known duplicate publications (10); other (60).

Question 1. Quality of Life

PCOS

1. Hoffman RM, Gilliland FD, Penson DF, Stone SN, Hunt WC, Potosky AL. Cross-sectional and longitudinal comparisons of health-related quality of life between patients with prostate carcinoma and matched controls. *Cancer* 2004;101(9):2011-9. *Previously published data*
2. Legler J, Potosky AL, Gilliland FD, et al. Validation Study of Retrospective Recall of Disease-Targeted Function: Results From the Prostate Cancer Outcomes Study. *Medical Care* 2000;38(8):847-57. *Validation study*
3. Penson DF, Feng Z, Kuniyuki A, et al. General Quality of Life 2 Years Following Treatment for Prostate Cancer: What Influences Outcomes? Results From the Prostate Cancer Outcomes Study. *J Clin Oncol* 2003;21:1147-54. *Not localized prostate cancer*
4. Potosky AL, Harlan LC, Stanford JL, et al. Prostate Cancer Practice Patterns and Quality of Life: the Prostate Cancer Outcomes Study. *Journal of the National Cancer Institute* 1999;91(20):1719-24. *No outcomes data*
5. Potosky AL, Knopf K, Clegg LX, et al. Quality-of-Life Outcomes After Primary Androgen Deprivation Therapy: Results >From the Prostate Cancer Outcomes Study. *J Clin Oncol* 2001;19:3750-57. *Not localized prostate cancer*
6. Potosky AL, Legler J, Albertsen PC, et al. Health outcomes after prostatectomy or radiotherapy for prostate cancer: results from the Prostate Cancer Outcomes Study. *Journal of the National Cancer Institute* 2000;92(19):1582-92. *Previously published data updated*
7. Potosky AL, Reeve BB, Clegg LX, et al. Quality of life following localized prostate cancer treated initially with androgen deprivation therapy or no therapy. *Journal of the National Cancer Institute* 2002;94(6):430-7. *Previously published data updated*

Appendix D: List of Excluded Studies (continued)

Non-PCOS

1. Abdalla I, Basu A, Hellman S. An evidence-based analysis of the management of localized prostate cancer. *Cancer Journal* 2002;8(1):40-6. *Review article*
2. Abouassaly R, Lane BR, Lakin MM, Klein EA, Gill IS. Ejaculatory urine incontinence after radical prostatectomy. *Urology* 2006 Dec;68(6):1248-52. *Less than 100 patients per study arm*
3. Agarwal PK, Oefelein MG. Testosterone replacement therapy after primary treatment for prostate cancer. *Journal of Urology* 2005;173(2):533-6. *Less than 100 patients per study arm*
4. Ahmad MM. Psychometric evaluation of the Cognitive Appraisal of Health Scale with patients with prostate cancer. *Journal of Advanced Nursing* 2005;49(1):78-86. *Not comparative treatments*
5. Ahmad MM, Musil CM, Zauszniewski JA, Resnick MI. Prostate cancer: appraisal, coping, and health status. *Journal of Gerontological Nursing* 2005;31(10):34-43. *Not comparative treatments*
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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Proton beam radiation therapy (PBRT), high-intensity focused ultrasound (HIFU), intensity modulated radiation therapy (IMRT), cryosurgery, and laparoscopic/robotic surgery

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13. Fricke ST, Rodriguez O, Vanmeter J, et al. In vivo magnetic resonance volumetric and spectroscopic analysis of mouse prostate cancer models. *Prostate* 2006;66(7):708-17. *Not human study.*
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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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41. Lee M, Wynne C, Webb S, et al. A comparison of proton and megavoltage X-ray treatment planning for prostate cancer. *Radiother Oncol* Dec 1994;33(3):239-53. *Not eligible outcomes.*
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.Michalski JM. Radiation therapy in the management of locally advanced prostate cancer. *Current Urology Reports* 2006;7(3):217-24. *Review.*
46. Mock U, Bogner J, Georg D, Auberger T, Potter R. Comparative treatment planning on localized prostate carcinoma conformal photon- versus proton-based radiotherapy. *Strahlentherapie und Onkologie* 2005;181(7):448-55. *Not eligible outcomes*
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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Question 3. Provider Characteristics Associated with Patient Outcomes

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix D: List of Excluded Studies (continued)

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Appendix E: Sample Abstraction Forms

Project Title Comparison of Therapies for Clinically Localized Prostate Cancer

Research question: How do provider/hospital characteristics affect outcomes overall and differentially (e.g. geographic region and volume)?

Abstraction Form (complete for each article)

Study ID (PUBMED) _____

Title: _____

Authors: _____

Reference: _____

Description of Database: _____

Abstractor: _____

VERIFICATION/SELECTION OF STUDY ELIGIBILITY

Language of the publication			
English	Yes	No	
Target population			
Patients with prostate adenocarcinoma	Yes	No	Combined
Stage of cancer			
I-II	Yes	No	Combined
Treatments			
Radical prostatectomy	Yes	No	
Radiation therapy	Yes	No	
Interstitial brachytherapy	Yes	No	
Cryosurgery	Yes	No	
Expectant management	Yes	No	
Hormonal therapy as primary therapy	Yes	No	
Provider characteristics			
Hospital volume	Yes	No	
Surgeon volume	Yes	No	
Hospital status	Yes	No	
Physician specialty	Yes	No	
Provider location	Yes	No	
Clinical outcomes			
Mortality	Yes	No	
Morbidity	Yes	No	
Urinary complications	Yes	No	
Long term incontinence	Yes	No	
Operational quality indicators	Yes	No	
Positive margins	Yes	No	
Length of stay	Yes	No	

Appendix E: Sample Abstraction Forms (continued)

Publication type (mark one)

- Published article
- Administrative report
- Dissertation
- Abstract/Presentation
- Book/book chapter

Purpose/aim of study _____

Design of the study (mark one)

- prospective cohort
- retrospective cohort
- cross-sectional
- descriptive study
- case-control
- case-series
- randomized controlled clinical trial
- not randomized clinical interventions
- ecologic

ASSESSMENT OF STUDY QUALITY

Score each domain on a scale of 0 (poor, not defined) to 5 (excellent, clearly defined)

1. Study question clearly focused and appropriate
2. The objectives and primary hypothesis of the study clearly stated
3. Description of the target population
4. Description and clear definition of the exposure
5. Description and clear definition of primary and secondary outcomes
6. Validation of the measurements of the exposure
7. Validation of the measurements of the outcomes
8. The process of the subjects' selection
9. The adequacy of the sampling (random selection or not)
10. The assessment of selection bias
11. Was the sample size justified
12. Censoring (when applicable)
13. Loss of followup
14. Length of followup (when applicable)
15. Assessment of possible confounding factors:
16. Validity of the measurements
17. Matching
18. Adjustment
19. Standardization
20. Measurement of possible effect measure modification
21. Reporting of the statistical analysis
22. Precision of the reported estimates of the association between exposure and outcomes (95% CI; maximum likelihood test, p value, the ratio of the highest 95% CI to the lowest)
23. Comparison of crude and adjusted estimates
24. Justification of the used models statistical models
25. Assessment of nonlinear associations
26. Appropriate multivariate-techniques to adjust for confounding factors (multivariate regression, propensity scores)
27. Subgroups analysis - Single site vs. multi center study
28. Limitations of the study
29. The major results of the study
30. The appropriate conclusions of the study
31. External validity of the study

Appendix E: Sample Abstraction Forms (continued)

Level of evidence of the individual study (mark one)

Interventions:

- I – Well-designed randomized controlled trial
- II-1A - Well-designed controlled trial with pseudo-randomization
- II-1B - Well-designed controlled trial without randomization

Observational studies

- I-2A - Well-designed cohort (prospective) study with concurrent controls
- II-2B - Well-designed cohort (prospective) study with historical controls
- II-2C - Well-designed cohort (retrospective) study with concurrent controls
- II-3 – Well-designed case-controlled (retrospective) study
- III – Large differences from comparisons between times and/or places
- Y – Opinion of respected authorities based in clinical experience

Source of sampling and data collection (define) _____

Country where the study was conducted _____

Financial Support: Industry, National Grant or foundations, other, define _____

Time interval outcomes occurred _____

Data to collect outcomes information: Administrative database, define _____
Medical Records _____

Adjustment for patient characteristics:

Patient age	Yes	No
Patient Race	Yes	No
Cancer stage	Yes	No
Patient Socio-economic Status	Yes	No
Patient Co morbidity	Yes	No

Hospital Affiliation with Medical School Yes NO

Patient Demographics

Number of patients (n, N, %): _____

Age (years, %): _____ Mean: _____ Min: _____ Max: _____ \pm SD: _____ \pm SE: _____

Race (n, %) White: _____ African-American: _____

Other: _____ Describe: _____

Tumor characteristics, Describe _____

Comments: _____

Appendix E: Sample Abstraction Forms (continued)

Patient Inclusion Criteria: _____

Patient Exclusion Criteria: _____

Surgeon Inclusion Criteria: _____

Surgeon Exclusion Criteria: _____

Group/Sub-Group Definitions

Group ID	Patients (n)	Define

Physician specialty: Urologist Radiation oncologist, General Internist, Other, define _____

Provider Location: State, Region, County, Other, define _____

Type of Volume

Hospital Volume

1. Number of patients: _____
2. Number of hospitals: _____
(e.g., low, medium, high)
3. Description: _____
4. Annual Volume, Define: _____
5. Mean: _____

1. Number of patients: _____
2. Number of hospitals: _____
(e.g., low, medium, high)
3. Description: _____
4. Annual Volume, Define: _____
5. Mean: _____

Comments: _____

Appendix E: Sample Abstraction Forms (continued)

Number of patients: _____

1. Number of hospitals: _____
(e.g., low, medium, high)
2. Description: _____
3. Annual Volume, Define: _____
4. Mean: _____

Comments:

Surgeon Volume

1. Number of patients: _____
(e.g., low, medium, high)
2. Description: _____
3. Annual Volume, Define: _____
4. Mean: _____
5. Median: _____

1. Number of patients: _____
(e.g., low, medium, high)
 2. Description: _____
 3. Annual Volume, Define: _____
 4. Mean: _____
- Median: _____

1. Number of patients: _____
(e.g., low, medium, high)
2. Description: _____
3. Annual Volume, Define: _____
4. Mean: _____
5. Median: _____

Appendix E: Sample Abstraction Forms (continued)

Treatment utilization	Outcomes				
	Rate/ 100,000 males	% of Treated/ diagnosed	Relative risk of treatment utilization	Cost \$	Length of stay, Days
Radical prostatectomy					
Radiation therapy					
Interstitial brachytherapy					
Cryosurgery					
Expectant management					
Hormonal therapy as primary therapy					

Comments: _____

Prostate Cancer screening, Incidence, and mortality

	PSA testing, %	Incidence total/100,000	Incidence, localized PC/100,000	Mortality total/ 100,000	Mortality, cancer specific/ 100,000
Provider characteristics					
Physician specialty					
Number of urologists					
Number of radiation oncologists					
Provider location					

Clinical outcomes in patients with prostate cancer treated with radical prostatectomy

Clinical outcomes	Events Standard Deviation	Rate Relative Risk, 95% CI
Surgery related mortality		
Morbidity		
Urinary complications		
Long-term incontinence		
Operational quality indicators		
Positive margins		
Blood loss		
Adjuvant therapy		
Length of stay		
Readmission		

Comments: _____

Appendix F: Definitions of Outcomes

- 1) Incidence of prostate cancer—the number of new cases per 100,000 age standardized male population during a given period of time
- 2) Prostate cancer screening—proportion of males who reported PSA testing at the state level
- 3) Mortality in patients with prostate cancer—all cause and prostate cancer deaths/100,000 age standardized male population during a given period of time
- 4) Treatment utilization—rate of radical prostatectomy per 100,000 age adjusted male population; percent of patients with localized prostate cancer receiving radical prostatectomy, external beam therapy, brachytherapy, primary androgen deprivation therapy, radiation, and watchful waiting as a primary treatment of prostate cancer
- 5) Intra-hospital mortality—crude and adjusted death rate from all causes during hospitalization and 30 days after submission in patients with prostate cancer treated with radical prostatectomy
- 6) Followup mortality—crude and adjusted death rate from all causes during the time of followup (90 days from surgery, 10 years from surgery) in patients with prostate cancer treated with radical prostatectomy
- 7) Positive surgical margins—proportion of the patients with extension of the tumor to the inked surface of the resected specimens
- 8) Intraoperation complication—proportion of the patients who needed blood transfusion during the prostatectomy
- 9) Volume of blood loss in ml. Postoperative complications—proportion of the patients with potentially life-threatening events during the 30 days after surgery in the following categories: cardiac, respiratory, or vascular events; the need for reoperation; bleeding; and other events including renal failure and shock
- 10) Late urinary complications—proportion of the patients treated for bladder-neck obstruction, urethral or ureteral strictures, intestinal or vesical fistulas, pelvic abscess, or any complication that resulted in early, definitive treatment of incontinence
- 11) Long-term incontinence—proportion of patients with symptoms of incontinence and the proportion of patients treated with corrective procedures, including periurethral injections of collagen or placement of an artificial urinary sphincter and other invasive procedures 24 months after prostatectomy
- 12) Failure of cancer control—proportion of patients treated with adjuvant hormone ablative therapy including orchiectomy, LupronT, goserelin and diethylstilbestrol
- 13) Length of hospital stay—number of overnight stays in the hospital
- 14) Cost—total hospital discharge in patients with localized prostate cancer in dollars
- 15) Readmission rate—proportion of patients who were readmitted to the hospital within 30 days after the operation
- 16) Operation quality indicators to assess radical prostatectomy specimens included: submission of a frozen section location of the adenocarcinoma, proportion of specimen involved by adenocarcinoma, perineural involvement, vascular involvement, seminal vesicle status, periprostate fat status, number of nodes submitted, status of nodes, and PIN (prostate intra-epithelial neoplasia)